

US3172333 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:36:34

All time stamps listed in this document are displayed in GMT

US3172333

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:31:21

Generated On: 09 Jun 2021 15:36:34

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Participant ID

US3172333

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

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US3172333

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

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

Visit date (dd MMM yyyy)	25 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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US3172333

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female <input checked="" type="radio"/> Male <input 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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Condition	HYPEROPIA
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:31:36

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:31:36

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:31:36

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	25 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:05 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:05
Height ( <i>xxx.x</i> )	174.5 cm
Weight ( <i>xxx.x</i> )	69.6 kg
BMI ( <i>xxx.x</i> )	22.85696 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 13:31:36

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Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 25 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:31:36

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:31:36

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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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

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

Visit date (dd MMM yyyy)	25 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 13:31:36

Generated On: 09 Jun 2021 15:36:34

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 108420

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:31:36

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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 13:31:36

Generated On: 09 Jun 2021 15:36:34

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)	25 AUG 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:05
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 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 13:31:36

Generated On: 09 Jun 2021 15:36:34

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)	25 AUG 2020
Time of assessment (00:00-23:59)	15:37 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:37
Temperature (xxx.x)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 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 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 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: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

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

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

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 17:07 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 17:07

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 13:31:36

Generated On: 09 Jun 2021 15:36:34

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

Collection date (dd MMM yyyy)	25 AUG 2020
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Collection time (00:00-23:59)	16:35 (24 HR)
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Collection date and time (derived)	25 AUG 2020 16:35
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US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:32	25 AUG 2020 16:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**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

99.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 25 AUG 2020 17:38

PC Open Date & Time 25 AUG 2020 17:27

PC Close Date & Time 25 AUG 2020 19:57

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	25 AUG 2020 23:26
PC Open Date & Time	25 AUG 2020 20:52
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

26 AUG 2020 12:35

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 14:14

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:53

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 19:21

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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

31 AUG 2020 11:09

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:30

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 17:39

PC Open Date & Time

25 AUG 2020 17:27

PC Close Date & Time

25 AUG 2020 19:57

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 23:27

PC Open Date & Time

25 AUG 2020 20:52

PC Close Date & Time

26 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**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

26 AUG 2020 12:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**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

27 AUG 2020 14:15

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:54

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**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

29 AUG 2020 19:22

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**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

31 AUG 2020 11:10

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**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

31 AUG 2020 20:31

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**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 ☐

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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

No ☐

Yes ☒

PC Time stamp	25 AUG 2020 17:40
PC Open Date & Time	25 AUG 2020 17:27
PC Close Date & Time	25 AUG 2020 19:57

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**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 ☐

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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

No ☐

Yes ☒

PC Time stamp	25 AUG 2020 23:27
PC Open Date & Time	25 AUG 2020 20:52
PC Close Date & Time	26 AUG 2020 11:59



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**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 ☐

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 12:37
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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 ☒

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EAB) (1725)

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 14:16
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**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

52 of 1774

EAB) (1725)

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:54
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 1774

EAB) (1725)

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:22
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 1774

EAB) (1725)

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:31
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3172333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172333

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172333

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172333

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

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

Visit date (dd MMM yyyy)	24 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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US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

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)	24 SEP 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 12:45
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 14:20
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3172333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 24 SEP 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 13:50

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



US3172333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

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

Collection date (dd MMM yyyy)	24 SEP 2020
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Collection time (00:00-23:59)	13:22 (24 HR)
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Collection date and time (derived)	24 SEP 2020 13:22
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US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:26	24 SEP 2020 13:26
Nasopharyngeal Swab 2	No		

US3172333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 14:21

PC Open Date & Time

24 SEP 2020 14:10

PC Close Date & Time

24 SEP 2020 16:40

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**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 98.7 °F

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

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

PC Time Stamp	25 SEP 2020 10:20
PC Open Date & Time	24 SEP 2020 17:35
PC Close Date & Time	25 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

25 SEP 2020 20:09

---

PC Open Date & Time

25 SEP 2020 12:00

---

PC Close Date & Time

26 SEP 2020 11:59

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US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 00:38

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:01

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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 SEP 2020 12:23

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:52

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**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

94.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 21:52

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 14:21

PC Open Date & Time

24 SEP 2020 14:10

PC Close Date & Time

24 SEP 2020 16:40

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 10:21

PC Open Date & Time

24 SEP 2020 17:35

PC Close Date & Time

25 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**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

25 SEP 2020 20:09

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**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

27 SEP 2020 00:38

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 20:01

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**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

28 SEP 2020 12:23

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 12:52

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**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

30 SEP 2020 21:52

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**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 ☐

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 14:22
PC Open Date & Time	24 SEP 2020 14:10
PC Close Date & Time	24 SEP 2020 16:40

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**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 ☐

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 10:22
PC Open Date & Time	24 SEP 2020 17:35
PC Close Date & Time	25 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**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 ☒

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EAB) (1725)



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:09
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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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US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 00:38
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**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

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EAB) (1725)

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:02
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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 ☒

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EAB) (1725)

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 12:23
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**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 ☒



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:52
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 21:53
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3172333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172333

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172333

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*



US3172333

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was this visit performed? Yes ☐  
No ☒

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

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

Folder OID VISIT3

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3172333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

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.*

US3172333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59



US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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 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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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 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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

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30 NOV 2020 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2020 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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 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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2020 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2020 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2020 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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

11 JAN 2021 14:09:21

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

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18 JAN 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 00:29:34

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 159

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

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

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

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

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

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

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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	28 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 FEB 2021 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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11 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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

22 FEB 2021 12:55:40

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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

25 FEB 2021 17:02:07

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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	06 MAR 2021 13:36:43
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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 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"/>



**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 18:01:01

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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

25 MAR 2021 00:08:36

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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

02 APR 2021 13:28:31

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 236

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

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

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

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

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

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

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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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="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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	20 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAY 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	27 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAY 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUN 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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="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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

12 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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 <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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	19 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59
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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	26 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	07 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59
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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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="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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 MAR 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 MAR 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 MAR 2022 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

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**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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="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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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 <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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	28 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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



US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

03 OCT 2022 23:59

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US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**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 ☐

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59



US3172333

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:36:34

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		02 MAR 2021 16:10:46

US3172333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172333

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:31:36

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

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

US3172333

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

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

US3172333

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3172333

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3172333**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:36:34**

Was this visit performed? Yes ☐  
No ☐

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

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

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

US3172333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

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

US3172333

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

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.*

US3172333

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

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

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

US3172333

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:35:11

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:35:11

Generated On: 09 Jun 2021 15:36:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172333

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:35:10

Generated On: 09 Jun 2021 15:36:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172333

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

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*

**US3172333**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:36:34**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172333

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:36:34

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"/>

**US3172333**

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

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

**Generated On: 09 Jun 2021 15:36:34**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

**US3172333**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:36:34**

Was this visit performed? Yes ☐  
No ☐

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

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

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

US3172333

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:34

Date of updated informed consent (*dd MMM yyyy*)

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3172333

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<input type="text"/>
Collection time ( <i>00:00-23:59</i> )	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

US3172333

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:34

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00 - 23:59</i> )	<hr/>
Collection Date and Time (derived)	<hr/>



US3172333

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:31:21

Generated On: 09 Jun 2021 15:36:34

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

AEID	USA-US118-2020-MRNA-1273-P30 1000011
Adverse event	BILATERAL ACUTE SALPINGITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	345 of 1774

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

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

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

---

ACUTE SALPINGITIS  
BILATERAL PRESENTING WITH  
ACUTE SEVERE PELVIC PAIN  
BILATERAL. MILD NAUSEA  
REQUIRING HOSPITALIZATION  
(11/9-11/12) AND ABS IUS. SHE IS  
CURRENTLY ASYMPTOMATIC,  
RECURRING AT HOME  
COMPLETING AND ABS CYCLE.  
WILL MONITOR OUTCOME.  
WILL REQUEST  
HOSPITALIZATION RECORDS  
FOR DETAILS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:31:21

Generated On: 09 Jun 2021 15:36:34

---

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

Yes ☒

No ☐

---

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

---

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE / LEFT DELTOID PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 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)		27 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE (SOLICITED  
ADVERSE REACTION, NOT AN  
A/E)

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE SALPINGITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

	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)		12 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE SALPINGITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172333

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 14:42:59

Generated On: 09 Jun 2021 15:36:34

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3172333

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:36:34

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3172333

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:34

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 ☐



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

SAEID	USA-US118-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

SAEID	USA-US118-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/NOV/2020 18:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

SAEID	USA-US118-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/DEC/2020 14:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

SAEID	USA-US118-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/FEB/2021 12:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 03 Mar 2021 13:59:21

Generated On: 09 Jun 2021 15:36:34

SAEID	USA-US118-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/MAR/2021 07:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3172333 (Prod: Suncoast Research Group LLC - ERN-PPDS)

**US3172333**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:36:34**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'US3172333'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:29:14

US3172333

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:22



US3172333

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:29:15

US3172333

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:22

**US3172333**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:36:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'SCRN'	System	26 Aug 2020 13:37:22

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:29:16

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '29'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'YEARS'	System	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '29'	System	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Female (F)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04



US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04



US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:04

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Aug 2020'	System	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2020'	System	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Amendment 3 (3)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:12:56



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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:12:56

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:29:15

US3172333

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'I'	System	25 Aug 2020 21:13:00

US3172333

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:36:34

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:13:00

US3172333

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:36:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:20

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:43:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:43:45
Data point term sent to Coder	System	26 Aug 2020 13:43:05
User entered 'HYPEROPIA'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:42:53

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'UN UNK 2001'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:42:53



US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:42:53

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:42:53

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:42:53

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:42:53

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Jan 2001'	System	26 Aug 2020 13:42:53

**US3172333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2001'	System	26 Aug 2020 13:42:53

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered empty.	System	26 Aug 2020 13:42:53

US3172333

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered empty.	System	26 Aug 2020 13:42:53



US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Kidney infection, LLT: Kidney infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:14:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:14:56
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:45:50
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'DATA UPDATED' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 19:56:42
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:02:49
Data point term sent to Coder	System	15 Oct 2020 20:25:26
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:25:10
User entered 'RECURRENT LEFT KIDNEY INFECTION' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:25:10
User closed query 'Per DM CLR: Please specify the type and location of KIDNEY INFECTION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:47:16

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Kidney infection, LLT: Kidney infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 13:55:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 13:55:44
Data point term sent to Coder	System	18 Sep 2020 20:02:07
Query 'Per DM CLR: Please specify the type and location of KIDNEY INFECTION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Data was updated.' (Site from DM). Coding entries removed.	Jessie Downs (b) (4) (b) (4)	18 Sep 2020 20:01:29
User entered 'LEFT KIDNEY INFECTION' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Sep 2020 20:01:07
User opened query 'Per DM CLR: Please specify the type and location of KIDNEY INFECTION. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:15:24
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Kidney infection, LLT: Kidney infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:45:48
Data point term sent to Coder	System	26 Aug 2020 13:44:06
User entered 'KIDNEY INFECTION'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'UN UNK 2019'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 19:57:03
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.'	(b) (4), (b) (6)	22 Oct 2020 03:22:42
(Site from DM).		
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:25:23
' answered with 'Data was updated.' (Site from DM).		
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.'	(b) (4), (b) (6)	15 Oct 2020 05:52:41
(Site from DM).		
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'un UNK 2019' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 19:57:03
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Jan 2019'	System	26 Aug 2020 13:43:06



US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2019'	System	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Jan 2019'	System	22 Oct 2020 19:57:03
User entered empty.	System	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2019'	System	22 Oct 2020 19:57:03
User entered empty.	System	26 Aug 2020 13:43:06

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Soft tissue therapeutic procedures NEC, PT: Liposuction, LLT: Liposuction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:45:48
Data point term sent to Coder	System	26 Aug 2020 13:44:07
User entered 'LIPOSUCTION'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:35



US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Jan 2017'	System	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2017'	System	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Jan 2017'	System	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2017'	System	26 Aug 2020 13:43:35

US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Maternal complications of pregnancy NEC, PT: Ectopic pregnancy, LLT: Ectopic pregnancy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:45:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 13:45:49
Data point term sent to Coder	System	26 Aug 2020 13:44:08
User entered 'ECTOPIC PREGNANCY'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:55

US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'UN UNK 2018'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:55

US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:55



US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:55

US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'UN UNK 2018'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:55

US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:43:55

US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Jan 2018'	System	26 Aug 2020 13:43:55

**US3172333**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:36:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2018'	System	26 Aug 2020 13:43:55

**US3172333**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:36:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'Jan 2018'	System	26 Aug 2020 13:43:55

US3172333

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:34

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '2018'	System	26 Aug 2020 13:43:55

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37



US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '15:05'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered '25 Aug 2020 15:05'	System	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '174.5' cm	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37
DataPoint set to visible.	System	25 Aug 2020 21:13:00

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '69.6' kg	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37
DataPoint set to visible.	System	25 Aug 2020 21:13:00

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
Amendment Manager: User entered '22.85696'	System	17 Sep 2020 00:02:43
User entered '22.9'	System	26 Aug 2020 13:38:37
DataPoint set to visible.	System	25 Aug 2020 21:13:00

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'kg/m2'	System	26 Aug 2020 13:38:37
DataPoint set to visible.	System	25 Aug 2020 21:13:00

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37



US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'bpm'	System	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'breaths/min'	System	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'mmHg'	System	26 Aug 2020 13:38:37



US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered 'mmHg'	System	26 Aug 2020 13:38:37

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48

US3172333

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48

US3172333

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:58:08
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:46

US3172333

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:58:08
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:46

US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52

US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52



US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52

US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52

US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52

US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52

US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52

US3172333

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:34

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:38:52

US3172333

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:06

US3172333

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:06



US3172333

Folder: Screening

Form: Pregnancy Test

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[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Urine (URINE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:06

US3172333

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Negative (NEGATIVE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:06

US3172333

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:06

US3172333

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:06

US3172333

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:06

**US3172333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:36:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User entered empty.	System	26 Aug 2020 13:39:06

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

**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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

**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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45



US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

**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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

**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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

[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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

**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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

**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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

[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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

**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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45



US3172333

Folder: Screening

Form: Risk of Exposure

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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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

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Folder: Screening

Form: Risk of Exposure

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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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

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Folder: Screening

Form: Risk of Exposure

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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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

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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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45



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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 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:37:45

US3172333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:21

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:37
	(b) (4)	
User entered '25 Aug 2020'	Mariete Rendon (b) (4)	26 Aug 2020 13:39:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

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 07:28:29
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:37
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	26 Aug 2020 13:39:21
	(b) (4)	

**US3172333**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:36:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'VISIT1'	System	26 Aug 2020 13:39:21

US3172333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:29:46



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:34

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '108420'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:29:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:34

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 20:29:46

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Folder: Visit 1 Day 1

Form: Randomization

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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 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:29

US3172333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:34

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 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:29

US3172333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:34

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:29

US3172333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:29

US3172333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:39:29

US3172333

Folder: Visit 1 Day 1

Form: Randomization

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[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:01:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:55:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:55:51



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '15:05'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '25 Aug 2020 15:05'	System	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '36.7' C	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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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 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '64'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'bpm'	System	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '15'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'breaths/min'	System	26 Aug 2020 13:40:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '106'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'mmHg'	System	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '69'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'mmHg'	System	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17



US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '15:37'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '25 Aug 2020 15:37'	System	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '37.4' C	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '73'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'bpm'	System	26 Aug 2020 13:40:17



US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '14'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'breaths/min'	System	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '109'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'mmHg'	System	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '71'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'mmHg'	System	26 Aug 2020 13:40:17

US3172333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:57:51
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:22

US3172333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:57:51
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:22



US3172333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:47:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:31

US3172333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:47:12
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:31

US3172333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:47:12
User entered 'Urine (URINE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:31

US3172333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:47:12
User entered 'Negative (NEGATIVE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:31

US3172333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 14:47:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:31

US3172333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:31

US3172333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:31

**US3172333**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:36:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered empty.	System	26 Aug 2020 13:40:31



US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

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 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:37
	(b) (4)	
User entered '25 Aug 2020'	Mariete Rendon (b) (4)	25 Aug 2020 21:13:31
	(b) (4)	

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '17:07'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '25 Aug 2020 17:07'	System	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	25 Aug 2020 21:13:31



US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'ONCE'	System	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 21:13:31

US3172333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:50

US3172333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:50

US3172333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '16:35'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:40:50

US3172333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '25 Aug 2020 16:35'	System	26 Aug 2020 13:40:50

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:36:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:02

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:02



US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:02

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '16:32'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:02

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '25 Aug 2020 16:32'	System	26 Aug 2020 13:41:02

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:02

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 15:29:18
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:02

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	17 Sep 2020 15:29:18
	(b) (4)	
User entered '16:32'	Mariete Rendon (b) (4)	26 Aug 2020 13:41:02
	(b) (4)	

US3172333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered empty.	System	17 Sep 2020 15:29:18
User entered '25 Aug 2020 16:32'	System	26 Aug 2020 13:41:02

US3172333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 13:41:07



US3172333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	26 Aug 2020 13:41:07

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:37:50', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61f246cd-c397-43d1-8363-f99f5491040b' User entered 'Yes (Y)'	System	25 Aug 2020 21:38:25
	System	25 Aug 2020 21:38:25

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:38:14', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61f246cd-c397-43d1-8363-f99f5491040b' User entered '99.2'	System	25 Aug 2020 21:38:25
	System	25 Aug 2020 21:38:25

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:38:20', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61f246cd-c397-43d1-8363-f99f5491040b'	System	25 Aug 2020 21:38:25
User entered 'No (N)'	System	25 Aug 2020 21:38:25

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:38:23', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61f246cd-c397-43d1-8363-f99f5491040b' User entered '25 Aug 2020 17:38'	System	25 Aug 2020 21:38:25
	System	25 Aug 2020 21:38:25

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 19:57'	System	25 Aug 2020 21:13:31



US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:24:17', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28df82de-2dec-4ec1-89e7-1247b5b9a406'	System	26 Aug 2020 03:26:50
User entered 'Yes (Y)'	System	26 Aug 2020 03:26:50

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:26:22', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28df82de-2dec-4ec1-89e7-1247b5b9a406' User entered '98.6'	System	26 Aug 2020 03:26:50
	System	26 Aug 2020 03:26:50

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:26:42', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28df82de-2dec-4ec1-89e7-1247b5b9a406'	System	26 Aug 2020 03:26:50
User entered 'No (N)'	System	26 Aug 2020 03:26:50

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:26:47', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28df82de-2dec-4ec1-89e7-1247b5b9a406'	System	26 Aug 2020 03:26:50
User entered '25 Aug 2020 23:26'	System	26 Aug 2020 03:26:50

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 20:52'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 2'	System	25 Aug 2020 21:13:31



US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:34:12', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '54ae80fd-d19a-431c-90cc-6aeb5f3cefe3' User entered 'Yes (Y)'	System	26 Aug 2020 16:35:51
	System	26 Aug 2020 16:35:51

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:35:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '54ae80fd-d19a-431c-90cc-6aeb5f3cefe3' User entered '97.1'	System	26 Aug 2020 16:35:51
	System	26 Aug 2020 16:35:51

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:35:45', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '54ae80fd-d19a-431c-90cc-6aeb5f3cefe3'	System	26 Aug 2020 16:35:51
User entered 'Yes (Y)'	System	26 Aug 2020 16:35:51

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data was updated ' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 15:26:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jessie Downs (b) (4)	10 Sep 2020 23:50:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:35:30', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '54ae80fd-d19a-431c-90cc-6aeb5f3cefe3'	(b) (4)	
User entered '1'	System	26 Aug 2020 16:35:51
	System	26 Aug 2020 16:35:51
	System	26 Aug 2020 16:35:51

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:35:30', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '54ae80fd-d19a-431c-90cc-6aeb5f3cefe3' User entered '0'	System	26 Aug 2020 16:35:51
	System	26 Aug 2020 16:35:51

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:35:48', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '54ae80fd-d19a-431c-90cc-6aeb5f3cefe3'	System	26 Aug 2020 16:35:51
User entered '26 Aug 2020 12:35'	System	26 Aug 2020 16:35:51

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:13:31



US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 3'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:13:11', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7ee4ac5-3586-484f-8168-7ae3afb811ab' User entered 'Yes (Y)'	System	27 Aug 2020 18:14:57
	System	27 Aug 2020 18:14:57

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:14:44', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7ee4ac5-3586-484f-8168-7ae3afb811ab' User entered '97.7'	System	27 Aug 2020 18:14:57
	System	27 Aug 2020 18:14:57

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:14:49', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7ee4ac5-3586-484f-8168-7ae3afb811ab' User entered 'No (N)'	System	27 Aug 2020 18:14:57
	System	27 Aug 2020 18:14:57

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:14:55', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7ee4ac5-3586-484f-8168-7ae3afb811ab' User entered '27 Aug 2020 14:14'	System	27 Aug 2020 18:14:57
	System	27 Aug 2020 18:14:57

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 4'	System	25 Aug 2020 21:13:31



US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:51:53', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bafb2792-de3b-46a1-b371-837b97077ad5' User entered 'Yes (Y)'	System	28 Aug 2020 16:53:49
	System	28 Aug 2020 16:53:49

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:53:33', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bafb2792-de3b-46a1-b371-837b97077ad5' User entered '97.3'	System	28 Aug 2020 16:53:49
	System	28 Aug 2020 16:53:49

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:53:39', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bafb2792-de3b-46a1-b371-837b97077ad5'	System	28 Aug 2020 16:53:49
User entered 'No (N)'	System	28 Aug 2020 16:53:49

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:53:45', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bafb2792-de3b-46a1-b371-837b97077ad5' User entered '28 Aug 2020 12:53'	System	28 Aug 2020 16:53:49
	System	28 Aug 2020 16:53:49

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 5'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:20:29', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9d47831a-7fd1-4a8f-aa80-5af2fac6aa7e' User entered 'Yes (Y)'	System	29 Aug 2020 23:21:50
	System	29 Aug 2020 23:21:50



US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:21:39', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9d47831a-7fd1-4a8f-aa80-5af2fac6aa7e' User entered '97.9'	System	29 Aug 2020 23:21:50
	System	29 Aug 2020 23:21:50

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:21:43', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9d47831a-7fd1-4a8f-aa80-5af2fac6aa7e' User entered 'No (N)'	System	29 Aug 2020 23:21:50
	System	29 Aug 2020 23:21:50

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:21:47', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9d47831a-7fd1-4a8f-aa80-5af2fac6aa7e' User entered '29 Aug 2020 19:21'	System	29 Aug 2020 23:21:50
	System	29 Aug 2020 23:21:50

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 6'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:07:02', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61555095-48d5-40a5-aa66-3e5281b23889' User entered 'Yes (Y)'	System	31 Aug 2020 15:11:55
	System	31 Aug 2020 15:11:55

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:09:06', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61555095-48d5-40a5-aa66-3e5281b23889' User entered '96.2'	System	31 Aug 2020 15:11:55
	System	31 Aug 2020 15:11:55



US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:09:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61555095-48d5-40a5-aa66-3e5281b23889'	System	31 Aug 2020 15:11:55
User entered 'No (N)'	System	31 Aug 2020 15:11:55

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:09:48', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '61555095-48d5-40a5-aa66-3e5281b23889'	System	31 Aug 2020 15:11:55
User entered '31 Aug 2020 11:09'	System	31 Aug 2020 15:11:55

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 7'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:30:30', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0d17509f-3196-4049-9eec-ad61694b3669' User entered 'Yes (Y)'	System	01 Sep 2020 00:30:55
	System	01 Sep 2020 00:30:55

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:30:37', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0d17509f-3196-4049-9eec-ad61694b3669' User entered '97.6'	System	01 Sep 2020 00:30:55
	System	01 Sep 2020 00:30:55

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:30:40', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0d17509f-3196-4049-9eec-ad61694b3669' User entered 'No (N)'	System	01 Sep 2020 00:30:55
	System	01 Sep 2020 00:30:55



US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:30:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0d17509f-3196-4049-9eec-ad61694b3669' User entered '31 Aug 2020 20:30'	System	01 Sep 2020 00:30:55
	System	01 Sep 2020 00:30:55

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:39:38', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '90fbefdd-7b6c-464d-a7e1-95b24eb8d9e8'	System	25 Aug 2020 21:40:25
User entered 'None (1)'	System	25 Aug 2020 21:40:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:39:47', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '90fbeffd-7b6c-464d-a7e1-95b24eb8d9e8'	System	25 Aug 2020 21:40:25
User entered 'No (N)'	System	25 Aug 2020 21:40:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:39:51', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '90fbeffd-7b6c-464d-a7e1-95b24eb8d9e8'	System	25 Aug 2020 21:40:25
User entered 'No (N)'	System	25 Aug 2020 21:40:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:39:56', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '90fbeffd-7b6c-464d-a7e1-95b24eb8d9e8'	System	25 Aug 2020 21:40:25
User entered 'None (1)'	System	25 Aug 2020 21:40:25



US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:39:59', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '90fbeffd-7b6c-464d-a7e1-95b24eb8d9e8'	System	25 Aug 2020 21:40:25
User entered '25 Aug 2020 17:39'	System	25 Aug 2020 21:40:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 19:57'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:26:54', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22ddac0d-7b44-4df6-87a3-a50557cbde4a' User entered 'None (1)'	System	26 Aug 2020 03:27:08
	System	26 Aug 2020 03:27:08

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:26:58', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22ddac0d-7b44-4df6-87a3-a50557cbde4a' User entered 'No (N)'	System	26 Aug 2020 03:27:08
	System	26 Aug 2020 03:27:08

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:01', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22ddac0d-7b44-4df6-87a3-a50557cbde4a' User entered 'No (N)'	System	26 Aug 2020 03:27:08
	System	26 Aug 2020 03:27:08

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22ddac0d-7b44-4df6-87a3-a50557cbde4a' User entered 'None (1)'	System	26 Aug 2020 03:27:08
	System	26 Aug 2020 03:27:08



**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:07', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22ddac0d-7b44-4df6-87a3-a50557cbde4a' User entered '25 Aug 2020 23:27'	System	26 Aug 2020 03:27:08
	System	26 Aug 2020 03:27:08

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 20:52'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 2'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:35:58', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '186a6554-c574-464b-ab86-94f1d7879a0f' User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 16:36:20
	System	26 Aug 2020 16:36:20

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:36:01', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '186a6554-c574-464b-ab86-94f1d7879a0f' User entered 'No (N)'	System	26 Aug 2020 16:36:20
	System	26 Aug 2020 16:36:20

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:36:05', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '186a6554-c574-464b-ab86-94f1d7879a0f' User entered 'No (N)'	System	26 Aug 2020 16:36:20
	System	26 Aug 2020 16:36:20

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:36:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '186a6554-c574-464b-ab86-94f1d7879a0f' User entered 'None (1)'	System	26 Aug 2020 16:36:20
	System	26 Aug 2020 16:36:20



**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:36:18', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '186a6554-c574-464b-ab86-94f1d7879a0f' User entered '26 Aug 2020 12:36'	System	26 Aug 2020 16:36:20
	System	26 Aug 2020 16:36:20

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 3'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '51ea5948-8367-4d4d-ac8e-f18accbe6a48'	System	27 Aug 2020 18:15:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 18:15:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:06', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '51ea5948-8367-4d4d-ac8e-f18accbe6a48' User entered 'No (N)'	System	27 Aug 2020 18:15:25
	System	27 Aug 2020 18:15:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:09', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '51ea5948-8367-4d4d-ac8e-f18accbe6a48' User entered 'No (N)'	System	27 Aug 2020 18:15:25
	System	27 Aug 2020 18:15:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '51ea5948-8367-4d4d-ac8e-f18accbe6a48'	System	27 Aug 2020 18:15:25
User entered 'None (1)'	System	27 Aug 2020 18:15:25



**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:18', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '51ea5948-8367-4d4d-ac8e-f18accbe6a48' User entered '27 Aug 2020 14:15'	System	27 Aug 2020 18:15:25
	System	27 Aug 2020 18:15:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 4'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:53:50', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0cc36ecd-56e7-44ae-8c87-03628f36414f' User entered 'None (1)'	System	28 Aug 2020 16:54:05
	System	28 Aug 2020 16:54:05

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:53:54', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0cc36ecd-56e7-44ae-8c87-03628f36414f' User entered 'No (N)'	System	28 Aug 2020 16:54:05
	System	28 Aug 2020 16:54:05

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:53:57', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0cc36ecd-56e7-44ae-8c87-03628f36414f' User entered 'No (N)'	System	28 Aug 2020 16:54:05
	System	28 Aug 2020 16:54:05

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:01', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0cc36ecd-56e7-44ae-8c87-03628f36414f' User entered 'None (1)'	System	28 Aug 2020 16:54:05
	System	28 Aug 2020 16:54:05



**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:04', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '0cc36ecd-56e7-44ae-8c87-03628f36414f' User entered '28 Aug 2020 12:54'	System	28 Aug 2020 16:54:05
	System	28 Aug 2020 16:54:05

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 5'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:21:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1a917dc8-0d80-4979-9078-e130256bdd6c' User entered 'None (1)'	System	29 Aug 2020 23:22:16
	System	29 Aug 2020 23:22:16

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:21:58', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1a917dc8-0d80-4979-9078-e130256bdd6c' User entered 'No (N)'	System	29 Aug 2020 23:22:16
	System	29 Aug 2020 23:22:16

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1a917dc8-0d80-4979-9078-e130256bdd6c' User entered 'No (N)'	System	29 Aug 2020 23:22:16
	System	29 Aug 2020 23:22:16

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:11', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1a917dc8-0d80-4979-9078-e130256bdd6c' User entered 'None (1)'	System	29 Aug 2020 23:22:16
	System	29 Aug 2020 23:22:16



**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1a917dc8-0d80-4979-9078-e130256bdd6c' User entered '29 Aug 2020 19:22'	System	29 Aug 2020 23:22:16
	System	29 Aug 2020 23:22:16

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 6'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:04', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c97710c0-e375-48b1-8e94-182bef57446a' User entered 'None (1)'	System	31 Aug 2020 15:12:25
	System	31 Aug 2020 15:12:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:07', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c97710c0-e375-48b1-8e94-182bef57446a' User entered 'No (N)'	System	31 Aug 2020 15:12:25
	System	31 Aug 2020 15:12:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c97710c0-e375-48b1-8e94-182bef57446a' User entered 'No (N)'	System	31 Aug 2020 15:12:25
	System	31 Aug 2020 15:12:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c97710c0-e375-48b1-8e94-182bef57446a' User entered 'None (1)'	System	31 Aug 2020 15:12:25
	System	31 Aug 2020 15:12:25



US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:19', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c97710c0-e375-48b1-8e94-182bef57446a' User entered '31 Aug 2020 11:10'	System	31 Aug 2020 15:12:25
	System	31 Aug 2020 15:12:25

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 7'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:30:57', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4c7ca37-e08b-4ac4-842b-690f9bcc2486'	System	01 Sep 2020 00:31:14
User entered 'None (1)'	System	01 Sep 2020 00:31:14

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:30:59', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4c7ca37-e08b-4ac4-842b-690f9bcc2486' User entered 'No (N)'	System	01 Sep 2020 00:31:14
	System	01 Sep 2020 00:31:14

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4c7ca37-e08b-4ac4-842b-690f9bcc2486' User entered 'No (N)'	System	01 Sep 2020 00:31:14
	System	01 Sep 2020 00:31:14

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:07', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4c7ca37-e08b-4ac4-842b-690f9bcc2486'	System	01 Sep 2020 00:31:14
User entered 'None (1)'	System	01 Sep 2020 00:31:14



US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:09', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4c7ca37-e08b-4ac4-842b-690f9bcc2486' User entered '31 Aug 2020 20:31'	System	01 Sep 2020 00:31:14
	System	01 Sep 2020 00:31:14

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:10', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered 'None (0)'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:14', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered 'None (0)'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:18', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered 'None (0)'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:21', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered 'None (0)'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:24', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered 'None (0)'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:27', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered 'None (0)'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:36', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered 'Yes (Y)'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T17:40:38', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bcb7e2ff-2eb2-4252-8962-799d988168d8' User entered '25 Aug 2020 17:40'	System	25 Aug 2020 21:40:40
	System	25 Aug 2020 21:40:40

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 19:57'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c' User entered 'None (0)'	System	26 Aug 2020 03:27:36
	System	26 Aug 2020 03:27:36



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:16', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c' User entered 'None (0)'	System	26 Aug 2020 03:27:36
	System	26 Aug 2020 03:27:36

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:18', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c' User entered 'None (0)'	System	26 Aug 2020 03:27:36
	System	26 Aug 2020 03:27:36

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:20', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c' User entered 'None (0)'	System	26 Aug 2020 03:27:36
	System	26 Aug 2020 03:27:36

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:21', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c' User entered 'None (0)'	System	26 Aug 2020 03:27:36
	System	26 Aug 2020 03:27:36

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:23', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c' User entered 'None (0)'	System	26 Aug 2020 03:27:36
	System	26 Aug 2020 03:27:36

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:29', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c'	System	26 Aug 2020 03:27:36
User entered 'Yes (Y)'	System	26 Aug 2020 03:27:36

**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-25T23:27:31', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '29e45a03-4a91-42db-b6bb-18921998877c' User entered '25 Aug 2020 23:27'	System	26 Aug 2020 03:27:36
	System	26 Aug 2020 03:27:36

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Aug 2020 20:52'	System	25 Aug 2020 21:13:31



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 2'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:36:42', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293'	System	26 Aug 2020 16:37:22
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:37:22

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:36:44', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293' User entered 'None (0)'	System	26 Aug 2020 16:37:22
	System	26 Aug 2020 16:37:22

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:36:50', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293' User entered 'None (0)'	System	26 Aug 2020 16:37:22
	System	26 Aug 2020 16:37:22

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:37:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293' User entered 'None (0)'	System	26 Aug 2020 16:37:22
	System	26 Aug 2020 16:37:22

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:37:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293' User entered 'None (0)'	System	26 Aug 2020 16:37:22
	System	26 Aug 2020 16:37:22

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:37:05', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293' User entered 'None (0)'	System	26 Aug 2020 16:37:22
	System	26 Aug 2020 16:37:22



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:37:16', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293'	System	26 Aug 2020 16:37:22
User entered 'Yes (Y)'	System	26 Aug 2020 16:37:22

**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-26T12:37:19', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1676de7e-d9f8-4e44-8701-4316f2229293'	System	26 Aug 2020 16:37:22
User entered '26 Aug 2020 12:37'	System	26 Aug 2020 16:37:22

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 3'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:28', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered 'None (0)'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:30', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered 'None (0)'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:35', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered 'None (0)'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:42', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered 'None (0)'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:45', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered 'None (0)'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:15:48', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered 'None (0)'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:16:06', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered 'No (N)'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14

**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-27T14:16:09', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '9f3863ae-0305-41b9-b11b-8f805447e40b' User entered '27 Aug 2020 14:16'	System	27 Aug 2020 18:16:14
	System	27 Aug 2020 18:16:14

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 4'	System	25 Aug 2020 21:13:31



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:09', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44' User entered 'None (0)'	System	28 Aug 2020 16:54:32
	System	28 Aug 2020 16:54:32

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:11', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44' User entered 'None (0)'	System	28 Aug 2020 16:54:32
	System	28 Aug 2020 16:54:32

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44' User entered 'None (0)'	System	28 Aug 2020 16:54:32
	System	28 Aug 2020 16:54:32

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44' User entered 'None (0)'	System	28 Aug 2020 16:54:32
	System	28 Aug 2020 16:54:32

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:17', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44' User entered 'None (0)'	System	28 Aug 2020 16:54:32
	System	28 Aug 2020 16:54:32

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:19', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44' User entered 'None (0)'	System	28 Aug 2020 16:54:32
	System	28 Aug 2020 16:54:32

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:26', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44'	System	28 Aug 2020 16:54:32
User entered 'No (N)'	System	28 Aug 2020 16:54:32

**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-28T12:54:29', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '2fea103f-b749-419a-af72-d3db145fdb44' User entered '28 Aug 2020 12:54'	System	28 Aug 2020 16:54:32
	System	28 Aug 2020 16:54:32



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 5'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:20', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered 'None (0)'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:22', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered 'None (0)'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:29', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered 'None (0)'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:33', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered 'None (0)'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51

**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:36:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:36', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered 'None (0)'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:39', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered 'None (0)'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:44', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered 'No (N)'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-29T19:22:46', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '53c6b2be-db51-4e9b-bcc5-3f6063b3b2e7' User entered '29 Aug 2020 19:22'	System	29 Aug 2020 23:22:51
	System	29 Aug 2020 23:22:51

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 6'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:28', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered 'None (0)'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:36', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered 'None (0)'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:48', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered 'None (0)'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:10:51', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered 'None (0)'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:11:01', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered 'None (0)'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:11:06', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered 'None (0)'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:11:11', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered 'No (N)'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T11:11:21', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '96e6fe86-c5f2-429a-b5e5-6db109c93f7d' User entered '31 Aug 2020 11:11'	System	31 Aug 2020 15:12:38
	System	31 Aug 2020 15:12:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:13:31



US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 7'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered 'None (0)'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered 'None (0)'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:19', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered 'None (0)'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:24', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered 'None (0)'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:26', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered 'None (0)'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:28', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered 'None (0)'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:33', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered 'No (N)'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38



**US3172333**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-08-31T20:31:35', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '28af1adf-9dcc-45c3-add2-75dc1a78635c' User entered '31 Aug 2020 20:31'	System	01 Sep 2020 00:31:38
	System	01 Sep 2020 00:31:38

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:13:31

US3172333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:18:58

US3172333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '02 Sep 2020'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:18:58

US3172333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:18:58

US3172333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:18:58

US3172333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:19:03



US3172333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	04 Sep 2020 18:19:03

US3172333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:29

US3172333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '09 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:29

US3172333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:29

US3172333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:29

US3172333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:34

US3172333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	17 Sep 2020 16:20:34

US3172333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:51



US3172333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:51

US3172333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:51

US3172333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:20:51

US3172333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:21:01

US3172333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	17 Sep 2020 16:21:01

US3172333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:59

US3172333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:59

US3172333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

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 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:59



**US3172333**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:36:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'VISIT2'	System	24 Sep 2020 17:58:59

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '12:45'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered '24 Sep 2020 12:45'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '37.0' C	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17



US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '73'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'bpm'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '15'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'breaths/min'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '99'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'mmHg'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '64'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17



US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'mmHg'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '14:20'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered '24 Sep 2020 14:20'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17



US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '65'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'bpm'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '14'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'breaths/min'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '104'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'mmHg'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '70'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:05:17



US3172333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'mmHg'	System	25 Sep 2020 15:05:17

US3172333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:18

US3172333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:18

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:44

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:44

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Urine (URINE)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:44

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Negative (NEGATIVE)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:44

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User closed query 'Per CDM: Per page 24 of CCGs, please remove the FSH sample collection date and time as FSH sample collected is "NO" Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:10:28
Query 'Per CDM: Per page 24 of CCGs, please remove the FSH sample collection date and time as FSH sample collected is "NO" Thank you. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 14:16:15
User opened query 'Per CDM: Per page 24 of CCGs, please remove the FSH sample collection date and time as FSH sample collected is "NO" Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 21:56:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:44



US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 14:16:11
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:02:44

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	02 Oct 2020 14:16:11
	(b) (4)	
User entered '12:47'	Jessie Downs (b) (4)	25 Sep 2020 15:02:44
	(b) (4)	

US3172333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:36:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered empty.	System	02 Oct 2020 14:16:11
User entered '24 Sep 2020 12:47'	System	25 Sep 2020 15:02:44

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

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 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:46



US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '13:50'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '24 Sep 2020 13:50'	System	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'ONCE'	System	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 17:58:46

US3172333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:16

US3172333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:16

US3172333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '13:22'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:16



US3172333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '24 Sep 2020 13:22'	System	25 Sep 2020 15:03:16

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:36:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '13:26'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '24 Sep 2020 13:26'	System	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:57:34
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:39



US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 15:57:34
User entered '13:26'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered empty.	System	05 Oct 2020 15:57:34
User entered '24 Sep 2020 13:26'	System	25 Sep 2020 15:03:39

US3172333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Sep 2020 15:03:44

US3172333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	25 Sep 2020 15:03:44

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:08', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22797815-a56c-4293-a4bf-2bc68c03fcde' User entered 'Yes (Y)'	System	24 Sep 2020 18:21:25
	System	24 Sep 2020 18:21:25

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22797815-a56c-4293-a4bf-2bc68c03fcde' User entered '98.1'	System	24 Sep 2020 18:21:25
	System	24 Sep 2020 18:21:25

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:18', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22797815-a56c-4293-a4bf-2bc68c03fcde' User entered 'No (N)'	System	24 Sep 2020 18:21:25
	System	24 Sep 2020 18:21:25



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:22', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '22797815-a56c-4293-a4bf-2bc68c03fcde' User entered '24 Sep 2020 14:21'	System	24 Sep 2020 18:21:25
	System	24 Sep 2020 18:21:25

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 14:10'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 16:40'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:18:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '44278aac-caef-4f1b-b836-0559baab5c2f' User entered 'Yes (Y)'	System	25 Sep 2020 14:20:39
	System	25 Sep 2020 14:20:39

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:20:24', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '44278aac-caef-4f1b-b836-0559baab5c2f' User entered '98.7'	System	25 Sep 2020 14:20:39
	System	25 Sep 2020 14:20:39

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:20:32', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '44278aac-caef-4f1b-b836-0559baab5c2f' User entered 'No (N)'	System	25 Sep 2020 14:20:39
	System	25 Sep 2020 14:20:39

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:20:35', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '44278aac-caef-4f1b-b836-0559baab5c2f' User entered '25 Sep 2020 10:20'	System	25 Sep 2020 14:20:39
	System	25 Sep 2020 14:20:39



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 17:35'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 2'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:08:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b62ea918-0c0f-4e35-b85b-23276e504189' User entered 'Yes (Y)'	System	26 Sep 2020 00:09:09
	System	26 Sep 2020 00:09:09

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:08:57', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b62ea918-0c0f-4e35-b85b-23276e504189' User entered '97.1'	System	26 Sep 2020 00:09:09
	System	26 Sep 2020 00:09:09

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:02', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b62ea918-0c0f-4e35-b85b-23276e504189'	System	26 Sep 2020 00:09:09
User entered 'No (N)'	System	26 Sep 2020 00:09:09

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:07', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b62ea918-0c0f-4e35-b85b-23276e504189' User entered '25 Sep 2020 20:09'	System	26 Sep 2020 00:09:09
	System	26 Sep 2020 00:09:09

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:58:46



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 3'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:36:09', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c1a2b902-8445-4021-8339-a39bb5500fba' User entered 'Yes (Y)'	System	27 Sep 2020 04:38:13
	System	27 Sep 2020 04:38:13

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:37:57', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c1a2b902-8445-4021-8339-a39bb5500fba' User entered '97.1'	System	27 Sep 2020 04:38:13
	System	27 Sep 2020 04:38:13

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:08', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c1a2b902-8445-4021-8339-a39bb5500fba' User entered 'No (N)'	System	27 Sep 2020 04:38:13
	System	27 Sep 2020 04:38:13

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:11', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c1a2b902-8445-4021-8339-a39bb5500fba' User entered '27 Sep 2020 00:38'	System	27 Sep 2020 04:38:13
	System	27 Sep 2020 04:38:13

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:58:46



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 4'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T19:59:17', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4538155-db98-4fe3-9723-9fa52d689b67' User entered 'Yes (Y)'	System	28 Sep 2020 00:01:24
	System	28 Sep 2020 00:01:24

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:11', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4538155-db98-4fe3-9723-9fa52d689b67' User entered '97.7'	System	28 Sep 2020 00:01:24
	System	28 Sep 2020 00:01:24

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:19', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4538155-db98-4fe3-9723-9fa52d689b67'	System	28 Sep 2020 00:01:24
User entered 'No (N)'	System	28 Sep 2020 00:01:24

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:22', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e4538155-db98-4fe3-9723-9fa52d689b67' User entered '27 Sep 2020 20:01'	System	28 Sep 2020 00:01:24
	System	28 Sep 2020 00:01:24

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 5'	System	24 Sep 2020 17:58:46



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:21:53', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d681fcf-c694-40fe-af51-cd2cbfdc3cc2'	System	28 Sep 2020 16:23:11
User entered 'Yes (Y)'	System	28 Sep 2020 16:23:11

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:22:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d681fcf-c694-40fe-af51-cd2cbfdc3cc2' User entered '97.0'	System	28 Sep 2020 16:23:11
	System	28 Sep 2020 16:23:11

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:06', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d681fcf-c694-40fe-af51-cd2cbfdc3cc2'	System	28 Sep 2020 16:23:11
User entered 'No (N)'	System	28 Sep 2020 16:23:11

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:08', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d681fcf-c694-40fe-af51-cd2cbfdc3cc2' User entered '28 Sep 2020 12:23'	System	28 Sep 2020 16:23:11
	System	28 Sep 2020 16:23:11

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 6'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:51:47', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '016f0b20-c33c-4a35-ad3f-8c7470fd43b1' User entered 'Yes (Y)'	System	29 Sep 2020 16:52:08
	System	29 Sep 2020 16:52:08



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:51:53', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '016f0b20-c33c-4a35-ad3f-8c7470fd43b1' User entered '97.1'	System	29 Sep 2020 16:52:08
	System	29 Sep 2020 16:52:08

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:51:57', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '016f0b20-c33c-4a35-ad3f-8c7470fd43b1'	System	29 Sep 2020 16:52:08
User entered 'No (N)'	System	29 Sep 2020 16:52:08

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:02', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '016f0b20-c33c-4a35-ad3f-8c7470fd43b1' User entered '29 Sep 2020 12:52'	System	29 Sep 2020 16:52:08
	System	29 Sep 2020 16:52:08

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 7'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:51:43', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f1376505-5a2e-47d7-a0d1-dda6f29cb751' User entered 'Yes (Y)'	System	01 Oct 2020 01:52:42
	System	01 Oct 2020 01:52:42

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:14', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f1376505-5a2e-47d7-a0d1-dda6f29cb751' User entered '94.5'	System	01 Oct 2020 01:52:42
	System	01 Oct 2020 01:52:42



US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:37', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f1376505-5a2e-47d7-a0d1-dda6f29cb751' User entered 'No (N)'	System	01 Oct 2020 01:52:42
	System	01 Oct 2020 01:52:42

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:40', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f1376505-5a2e-47d7-a0d1-dda6f29cb751' User entered '30 Sep 2020 21:52'	System	01 Oct 2020 01:52:42
	System	01 Oct 2020 01:52:42

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:26', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ac1bad79-5153-487c-a23a-6b47ac2d6905'	System	24 Sep 2020 18:21:41
User entered 'None (1)'	System	24 Sep 2020 18:21:41

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:30', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ac1bad79-5153-487c-a23a-6b47ac2d6905' User entered 'No (N)'	System	24 Sep 2020 18:21:41
	System	24 Sep 2020 18:21:41

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:32', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ac1bad79-5153-487c-a23a-6b47ac2d6905' User entered 'No (N)'	System	24 Sep 2020 18:21:41
	System	24 Sep 2020 18:21:41



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:36', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ac1bad79-5153-487c-a23a-6b47ac2d6905'	System	24 Sep 2020 18:21:41
User entered 'None (1)'	System	24 Sep 2020 18:21:41

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:38', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ac1bad79-5153-487c-a23a-6b47ac2d6905' User entered '24 Sep 2020 14:21'	System	24 Sep 2020 18:21:41
	System	24 Sep 2020 18:21:41

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 14:10'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 16:40'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:20:48', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bad0c099-ba59-43fc-98d8-69e224b0220a'	System	25 Sep 2020 14:21:27
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 14:21:27

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:20:51', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bad0c099-ba59-43fc-98d8-69e224b0220a' User entered 'No (N)'	System	25 Sep 2020 14:21:27
	System	25 Sep 2020 14:21:27

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bad0c099-ba59-43fc-98d8-69e224b0220a' User entered 'No (N)'	System	25 Sep 2020 14:21:27
	System	25 Sep 2020 14:21:27



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:23', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bad0c099-ba59-43fc-98d8-69e224b0220a' User entered 'None (1)'	System	25 Sep 2020 14:21:27
	System	25 Sep 2020 14:21:27

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:26', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'bad0c099-ba59-43fc-98d8-69e224b0220a' User entered '25 Sep 2020 10:21'	System	25 Sep 2020 14:21:27
	System	25 Sep 2020 14:21:27

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 17:35'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 2'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:11', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7cc5823-acf1-43a3-b5bb-be89cf3753e6'	System	26 Sep 2020 00:09:25
User entered 'None (1)'	System	26 Sep 2020 00:09:25

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7cc5823-acf1-43a3-b5bb-be89cf3753e6' User entered 'No (N)'	System	26 Sep 2020 00:09:25
	System	26 Sep 2020 00:09:25

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:17', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7cc5823-acf1-43a3-b5bb-be89cf3753e6' User entered 'No (N)'	System	26 Sep 2020 00:09:25
	System	26 Sep 2020 00:09:25



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:20', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7cc5823-acf1-43a3-b5bb-be89cf3753e6'	System	26 Sep 2020 00:09:25
User entered 'None (1)'	System	26 Sep 2020 00:09:25

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:22', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'e7cc5823-acf1-43a3-b5bb-be89cf3753e6' User entered '25 Sep 2020 20:09'	System	26 Sep 2020 00:09:25
	System	26 Sep 2020 00:09:25

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 3'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:14', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d74389c-80e7-49ec-abc7-e7e71266c98c' User entered 'None (1)'	System	27 Sep 2020 04:38:30
	System	27 Sep 2020 04:38:30

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:17', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d74389c-80e7-49ec-abc7-e7e71266c98c' User entered 'No (N)'	System	27 Sep 2020 04:38:30
	System	27 Sep 2020 04:38:30

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:21', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d74389c-80e7-49ec-abc7-e7e71266c98c' User entered 'No (N)'	System	27 Sep 2020 04:38:30
	System	27 Sep 2020 04:38:30



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:24', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d74389c-80e7-49ec-abc7-e7e71266c98c' User entered 'None (1)'	System	27 Sep 2020 04:38:30
	System	27 Sep 2020 04:38:30

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:28', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d74389c-80e7-49ec-abc7-e7e71266c98c' User entered '27 Sep 2020 00:38'	System	27 Sep 2020 04:38:30
	System	27 Sep 2020 04:38:30

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 4'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:34', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '8c232cad-e4c3-49a7-ad5a-da982186f700' User entered 'None (1)'	System	28 Sep 2020 00:01:49
	System	28 Sep 2020 00:01:49

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:37', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '8c232cad-e4c3-49a7-ad5a-da982186f700' User entered 'No (N)'	System	28 Sep 2020 00:01:49
	System	28 Sep 2020 00:01:49

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:41', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '8c232cad-e4c3-49a7-ad5a-da982186f700' User entered 'No (N)'	System	28 Sep 2020 00:01:49
	System	28 Sep 2020 00:01:49



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:43', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '8c232cad-e4c3-49a7-ad5a-da982186f700' User entered 'None (1)'	System	28 Sep 2020 00:01:49
	System	28 Sep 2020 00:01:49

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:47', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '8c232cad-e4c3-49a7-ad5a-da982186f700' User entered '27 Sep 2020 20:01'	System	28 Sep 2020 00:01:49
	System	28 Sep 2020 00:01:49

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 5'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:13', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '6e87fbf0-d108-4850-aa63-8a1d1de8617e' User entered 'None (1)'	System	28 Sep 2020 16:23:24
	System	28 Sep 2020 16:23:24

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:16', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '6e87fbf0-d108-4850-aa63-8a1d1de8617e' User entered 'No (N)'	System	28 Sep 2020 16:23:24
	System	28 Sep 2020 16:23:24

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:18', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '6e87fbf0-d108-4850-aa63-8a1d1de8617e' User entered 'No (N)'	System	28 Sep 2020 16:23:24
	System	28 Sep 2020 16:23:24



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:20', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '6e87fbf0-d108-4850-aa63-8a1d1de8617e' User entered 'None (1)'	System	28 Sep 2020 16:23:24
	System	28 Sep 2020 16:23:24

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:23', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '6e87fbf0-d108-4850-aa63-8a1d1de8617e' User entered '28 Sep 2020 12:23'	System	28 Sep 2020 16:23:24
	System	28 Sep 2020 16:23:24

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 6'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:06', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c64b0d1e-f2c5-441d-adec-6dedb211db71' User entered 'None (1)'	System	29 Sep 2020 16:52:22
	System	29 Sep 2020 16:52:22

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:09', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c64b0d1e-f2c5-441d-adec-6dedb211db71' User entered 'No (N)'	System	29 Sep 2020 16:52:22
	System	29 Sep 2020 16:52:22

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:10', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c64b0d1e-f2c5-441d-adec-6dedb211db71' User entered 'No (N)'	System	29 Sep 2020 16:52:22
	System	29 Sep 2020 16:52:22



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:15', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c64b0d1e-f2c5-441d-adec-6dedb211db71' User entered 'None (1)'	System	29 Sep 2020 16:52:22
	System	29 Sep 2020 16:52:22

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:17', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c64b0d1e-f2c5-441d-adec-6dedb211db71' User entered '29 Sep 2020 12:52'	System	29 Sep 2020 16:52:22
	System	29 Sep 2020 16:52:22

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 7'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:43', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7cc82285-2fa1-4aaf-93f0-6984ddeb09ad'	System	01 Oct 2020 01:52:58
User entered 'None (1)'	System	01 Oct 2020 01:52:58

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:46', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7cc82285-2fa1-4aaf-93f0-6984ddeb09ad' User entered 'No (N)'	System	01 Oct 2020 01:52:58
	System	01 Oct 2020 01:52:58

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:49', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7cc82285-2fa1-4aaf-93f0-6984ddeb09ad'	System	01 Oct 2020 01:52:58
User entered 'No (N)'	System	01 Oct 2020 01:52:58



US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:54', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7cc82285-2fa1-4aaf-93f0-6984ddeb09ad'	System	01 Oct 2020 01:52:58
User entered 'None (1)'	System	01 Oct 2020 01:52:58

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:52:56', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7cc82285-2fa1-4aaf-93f0-6984ddeb09ad' User entered '30 Sep 2020 21:52'	System	01 Oct 2020 01:52:58
	System	01 Oct 2020 01:52:58

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:42', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered 'None (0)'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:45', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered 'None (0)'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:47', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered 'None (0)'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:51', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered 'None (0)'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:53', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered 'None (0)'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:55', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered 'None (0)'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:21:58', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered 'No (N)'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-24T14:22:01', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b4c36556-9518-45fc-855f-5f8c6e73e649' User entered '24 Sep 2020 14:22'	System	24 Sep 2020 18:22:04
	System	24 Sep 2020 18:22:04

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 14:10'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 16:40'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 17:58:46



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:33', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79'	System	25 Sep 2020 14:22:08
User entered 'No interference with activity (1)'	System	25 Sep 2020 14:22:08

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:37', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79' User entered 'None (0)'	System	25 Sep 2020 14:22:08
	System	25 Sep 2020 14:22:08

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:41', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79'	System	25 Sep 2020 14:22:08
User entered 'No interference with activity (1)'	System	25 Sep 2020 14:22:08

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:48', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79'	System	25 Sep 2020 14:22:08
User entered 'No interference with activity (1)'	System	25 Sep 2020 14:22:08

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79' User entered 'None (0)'	System	25 Sep 2020 14:22:08
	System	25 Sep 2020 14:22:08

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:21:55', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79' User entered 'None (0)'	System	25 Sep 2020 14:22:08
	System	25 Sep 2020 14:22:08

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:22:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79' User entered 'No (N)'	System	25 Sep 2020 14:22:08
	System	25 Sep 2020 14:22:08

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T10:22:06', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'f2c1bcec-30be-4053-bd33-21d701cc6b79' User entered '25 Sep 2020 10:22'	System	25 Sep 2020 14:22:08
	System	25 Sep 2020 14:22:08



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '24 Sep 2020 17:35'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 2'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:25', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered 'None (0)'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:26', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered 'None (0)'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:28', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered 'None (0)'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:31', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered 'None (0)'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:33', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered 'None (0)'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:34', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered 'None (0)'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:37', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered 'No (N)'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-25T20:09:39', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7e1d2c7b-0d18-4b27-b248-3413f5ea0eb5' User entered '25 Sep 2020 20:09'	System	26 Sep 2020 00:09:41
	System	26 Sep 2020 00:09:41

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 3'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:32', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered 'None (0)'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:34', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered 'None (0)'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:38', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered 'None (0)'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:45', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered 'None (0)'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:47', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered 'None (0)'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:49', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered 'None (0)'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered 'No (N)'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T00:38:55', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'dccbf4b7-e2a8-4571-947b-19549af03032' User entered '27 Sep 2020 00:38'	System	27 Sep 2020 04:38:57
	System	27 Sep 2020 04:38:57

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 17:58:46



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 4'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:01:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered 'None (0)'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:02:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered 'None (0)'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:02:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered 'None (0)'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:02:05', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered 'None (0)'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:02:08', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered 'None (0)'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:02:12', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered 'None (0)'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:02:25', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered 'No (N)'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-27T20:02:27', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'ee728459-f357-4986-afb1-7457b14ca282' User entered '27 Sep 2020 20:02'	System	28 Sep 2020 00:02:28
	System	28 Sep 2020 00:02:28

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 5'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:41', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered 'None (0)'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:43', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered 'None (0)'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:46', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered 'None (0)'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:48', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered 'None (0)'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:50', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered 'None (0)'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:52', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered 'None (0)'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:56', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered 'No (N)'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-28T12:23:58', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b12ef87a-c3a9-45ac-a886-1988bd718dba' User entered '28 Sep 2020 12:23'	System	28 Sep 2020 16:24:02
	System	28 Sep 2020 16:24:02

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 6'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:21', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered 'None (0)'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:24', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered 'None (0)'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:27', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered 'None (0)'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:29', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered 'None (0)'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:30', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered 'None (0)'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:31', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered 'None (0)'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:34', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered 'No (N)'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-29T12:52:36', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '270f367d-adc8-4196-9221-eb568cb4fd20' User entered '29 Sep 2020 12:52'	System	29 Sep 2020 16:52:40
	System	29 Sep 2020 16:52:40

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 17:58:46



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
Data entry locked.	System	24 Sep 2020 17:58:46
User entered 'Day 7'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered 'None (0)'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:01', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered 'None (0)'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:03', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered 'None (0)'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:04', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered 'None (0)'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:07', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered 'None (0)'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:09', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered 'None (0)'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16



US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

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 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:12', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered 'No (N)'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16

**US3172333**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:36:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D29A3D2-44F9-4299-901D-5FE7494BF341)', Time: '2020-09-30T21:53:14', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '1dea58c7-4011-4bbd-be79-fcc9a1088a15' User entered '30 Sep 2020 21:53'	System	01 Oct 2020 01:53:16
	System	01 Oct 2020 01:53:16

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 17:58:46

US3172333

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:36:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:56:11
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 17:58:46

US3172333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 19:49:25

US3172333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '1 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 19:49:25

US3172333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 19:49:25

US3172333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 19:49:25



US3172333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:27:51
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:57:55
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 19:49:43

US3172333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered '1'	System	15 Oct 2020 20:27:51
User entered empty.	System	07 Oct 2020 17:57:55
User entered '1'	System	02 Oct 2020 19:49:43

US3172333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:16

US3172333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '08 Oct 2020'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:16

US3172333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:16

US3172333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:16

US3172333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:21

**US3172333**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:36:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	15 Oct 2020 20:28:21



US3172333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:38

US3172333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '15 Oct 2020'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:38

US3172333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:38

US3172333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:38

US3172333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:48
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Oct 2020 20:28:50

US3172333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	20 Nov 2020 22:13:48
User entered empty.	System	15 Oct 2020 20:28:50

US3172333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:55

US3172333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:55



US3172333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:34

[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 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:55

**US3172333**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:36:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'VISIT3'	System	20 Nov 2020 22:13:55

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered empty.	System	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01



US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered empty.	System	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered empty.	System	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered empty.	System	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:01



US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered empty.	System	20 Nov 2020 22:14:01

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30

US3172333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30

US3172333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:05

US3172333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:05

US3172333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:10

US3172333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:10

US3172333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:10



US3172333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered empty.	System	20 Nov 2020 22:14:10

US3172333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:14

**US3172333**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:36:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:30
User entered 'I'	System	20 Nov 2020 22:14:14

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 64'	System	25 Aug 2020 21:13:31

US3172333

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Please 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Please 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Please 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 21:13:31

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 71'	System	25 Aug 2020 21:13:31



US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

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

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**Generated On: 09 Jun 2021 15:36:34**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Please 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

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[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 12:36:24
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**Folder: Safety Follow Up Diary (1)**

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Audit	User	Time (GMT)
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[Date and time of submission](#)

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Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 21:13:31

**US3172333**

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

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 21:13:31

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

Audit	User	Time (GMT)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered 'Day 78'	System	25 Aug 2020 21:13:31

US3172333

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 12:36:24
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US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

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

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

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Please 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

US3172333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

[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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Please 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 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 21:13:31

**US3172333**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:44:54
Data entry locked.	System	25 Aug 2020 21:13:31
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 21:13:31

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-01-11T14:09:14', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d808c14-9f40-4981-9eb5-6ba996f26936'	System	11 Jan 2021 19:09:28
User entered 'No (N)'	System	11 Jan 2021 19:09:28

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-01-11T14:09:19', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d808c14-9f40-4981-9eb5-6ba996f26936'	System	11 Jan 2021 19:09:28
User entered 'No (N)'	System	11 Jan 2021 19:09:28

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-01-11T14:09:21', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '4d808c14-9f40-4981-9eb5-6ba996f26936' User entered '11 Jan 2021 14:09:21'	System	11 Jan 2021 19:09:28
	System	11 Jan 2021 19:09:28



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-01-22T00:29:28', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7422898d-7f65-44ca-a706-71d6865b8026'	System	22 Jan 2021 05:29:38
User entered 'No (N)'	System	22 Jan 2021 05:29:38

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-01-22T00:29:31', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7422898d-7f65-44ca-a706-71d6865b8026'	System	22 Jan 2021 05:29:38
User entered 'No (N)'	System	22 Jan 2021 05:29:38



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-01-22T00:29:34', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '7422898d-7f65-44ca-a706-71d6865b8026' User entered '22 Jan 2021 00:29:34'	System	22 Jan 2021 05:29:38
	System	22 Jan 2021 05:29:38

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-02-22T12:55:33', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '56d70260-55e4-4f68-85da-f32f8655a7c2'	System	22 Feb 2021 17:55:43
User entered 'No (N)'	System	22 Feb 2021 17:55:43

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-02-22T12:55:37', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '56d70260-55e4-4f68-85da-f32f8655a7c2'	System	22 Feb 2021 17:55:43
User entered 'No (N)'	System	22 Feb 2021 17:55:43

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-02-22T12:55:40', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '56d70260-55e4-4f68-85da-f32f8655a7c2'	System	22 Feb 2021 17:55:43
User entered '22 Feb 2021 12:55:40'	System	22 Feb 2021 17:55:43



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-02-25T12:01:59-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '570e2bd9-b553-4ede-b688-851ff2e7ba1a' User entered 'No (N)'	System	25 Feb 2021 17:07:08
	System	25 Feb 2021 17:07:08

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-02-25T12:02:03-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '570e2bd9-b553-4ede-b688-851ff2e7ba1a' User entered 'No (N)'	System	25 Feb 2021 17:07:08
	System	25 Feb 2021 17:07:08

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-02-25T12:02:07-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '570e2bd9-b553-4ede-b688-851ff2e7ba1a' User entered '25 Feb 2021 17:02:07'	System	25 Feb 2021 17:07:08
	System	25 Feb 2021 17:07:08

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-06T13:36:35-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c5dfe610-3eba-48ca-8821-439cfe7158f3'	System	06 Mar 2021 18:36:48
User entered 'No (N)'	System	06 Mar 2021 18:36:48

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-06T13:36:40-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c5dfe610-3eba-48ca-8821-439cfe7158f3'	System	06 Mar 2021 18:36:48
User entered 'No (N)'	System	06 Mar 2021 18:36:48

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-06T13:36:43-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c5dfe610-3eba-48ca-8821-439cfe7158f3'	System	06 Mar 2021 18:36:48
User entered '06 Mar 2021 13:36:43'	System	06 Mar 2021 18:36:48

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-21T18:00:51-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b3d9bdca-2493-49c0-851a-0b207573c456'	System	21 Mar 2021 22:03:20
User entered 'No (N)'	System	21 Mar 2021 22:03:20

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-21T18:00:58-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b3d9bdca-2493-49c0-851a-0b207573c456'	System	21 Mar 2021 22:03:20
User entered 'No (N)'	System	21 Mar 2021 22:03:20

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-21T18:01:01-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'b3d9bdca-2493-49c0-851a-0b207573c456'	System	21 Mar 2021 22:03:20
User entered '21 Mar 2021 18:01:01'	System	21 Mar 2021 22:03:20

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-25T00:08:25-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c39c5d3a-2120-457c-8e67-27cabda6fed1'	System	25 Mar 2021 04:08:39
User entered 'No (N)'	System	25 Mar 2021 04:08:39

US3172333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:34

Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-25T00:08:33-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c39c5d3a-2120-457c-8e67-27cabda6fed1'	System	25 Mar 2021 04:08:39
User entered 'No (N)'	System	25 Mar 2021 04:08:39

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-25T00:08:36-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: 'c39c5d3a-2120-457c-8e67-27cabda6fed1' User entered '25 Mar 2021 00:08:36'	System	25 Mar 2021 04:08:39
	System	25 Mar 2021 04:08:39

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-04-02T13:28:25-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '33ae41ea-ba21-4c1b-bb2f-cfda15d6cbd1' User entered 'No (N)'	System	02 Apr 2021 17:28:35
	System	02 Apr 2021 17:28:35

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Have you been exposed to someone with 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 (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-04-02T13:28:28-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '33ae41ea-ba21-4c1b-bb2f-cfda15d6cbd1'	System	02 Apr 2021 17:28:35
User entered 'No (N)'	System	02 Apr 2021 17:28:35



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-04-02T13:28:31-04:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '33ae41ea-ba21-4c1b-bb2f-cfda15d6cbd1' User entered '02 Apr 2021 13:28:31'	System	02 Apr 2021 17:28:35
	System	02 Apr 2021 17:28:35

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:44:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:44:54

**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:44:54



**US3172333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:36:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:54
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:44:54

US3172333

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:36:34**

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 12:36:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-02T16:10:43-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '79dd550c-6c72-4a40-a6f6-e204c1771245'	System	02 Mar 2021 21:10:50
User entered 'No (N)'	System	02 Mar 2021 21:10:50

**US3172333**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:36:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5337B7F1-84E1-414E-910B-8959E8CEFC51)', Time: '2021-03-02T16:10:46-05:00', User OID: 'PatientReportedOutcome (US3172333)', ODM File OID: '79dd550c-6c72-4a40-a6f6-e204c1771245'	System	02 Mar 2021 21:10:50
User entered '02 Mar 2021 16:10:46'	System	02 Mar 2021 21:10:50

US3172333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:30

US3172333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered '20 Nov 2020'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:30

US3172333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:30

US3172333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:30

US3172333

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:14:57



**US3172333**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:36:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:28:29
User entered 'I'	System	20 Nov 2020 22:14:57

US3172333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:33:28

US3172333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:33:28

US3172333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:33:28

US3172333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'missed.'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:33:28

US3172333

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:26:06

US3172333

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User entered 'I'	System	24 Feb 2021 18:26:06

US3172333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:35:00



US3172333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:35:00

US3172333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:35:00

US3172333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'missed.'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 20:35:00

US3172333

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:26:13

US3172333

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User entered 'I'	System	24 Feb 2021 18:26:13

US3172333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:26:27

US3172333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:26:27

US3172333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:26:27



US3172333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:26:27

US3172333

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:26:31

US3172333

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:35:00
User entered 'I'	System	24 Feb 2021 18:26:31

US3172333

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 13:46:33

**US3172333**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:36:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 13:46:33

US3172333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 13:46:46

US3172333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:11
User entered '21 Apr 2021'	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 13:46:46

US3172333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:11
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 13:46:46



US3172333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 13:46:46

US3172333

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:35:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 13:46:51

**US3172333**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:36:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 13:46:51

US3172333

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:36:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:04:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:56:43
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 16:21:14

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 12:25:04
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 12:25:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:41:09
User entered	System	23 Nov 2020 23:41:05
'USA-US118-2020-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 23:41:05

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Female reproductive tract infections, PT: Salpingitis, LLT: Acute salpingitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:02:05
Data point term sent to Coder	System	20 Nov 2020 22:00:34
User entered 'Bilateral Acute Salpingitis'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40



US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

US3172333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '09 Nov 2020'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Nov 2020 22:11:21
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	20 Nov 2020 22:11:21
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Nov 2020 21:59:40
User entered '16:00'	Jessie Downs (b) (4)	20 Nov 2020 21:59:40
	(b) (4)	

**US3172333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:36:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 22:11:21
User entered '09 Nov 2020 16:00'	System	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	24 Feb 2021 18:20:39
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 19:03:20
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	20 Nov 2020 21:59:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:31:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Date was added ' (Site from Safety).	Jessie Downs (b) (4)	24 Feb 2021 18:22:37
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Feb 2021 18:20:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Feb 2021 18:20:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Feb 2021 18:20:39
User entered '26 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	24 Feb 2021 18:20:39
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 19:03:23
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:40:39
User entered empty.	Jessie Downs (b) (4)	20 Nov 2020 21:59:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Feb 2021 18:22:04
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	24 Feb 2021 18:22:04
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Feb 2021 18:21:46
User entered '08:00' reason for change: Data Entry Error	Jessie Downs (b) (4)	24 Feb 2021 18:21:46
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	20 Nov 2020 21:59:40
	(b) (4)	

**US3172333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:36:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 18:22:04
User entered '26 Nov 2020 08:00'	System	24 Feb 2021 18:21:46
User entered empty.	System	20 Nov 2020 21:59:40



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' canceled (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 15:20:01
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:41:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4)	20 Nov 2020 21:59:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'I'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '09 Nov 2020'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '12 Nov 2020'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40



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Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40



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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:49
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered 'l'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:51
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 03:07:45
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:48:37
User entered '0' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:48:14
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:37:48
User entered '1'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:31:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data updated' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:22:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:20:57
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:40:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:55
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 21:59:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:06:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:42:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' answered with 'Pending medical records ' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 20:39:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 16:02:27
User closed query 'PV Query: Please clarify what ABS means in relation to ABS IUS in narrative.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:02:15
User closed query 'PV Query: Please confirm if the subject had an intrauterine system (IUS) placed during this event.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:02:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:02:09
Query 'PV Query: Please clarify what ABS means in relation to ABS IUS in narrative.' answered with 'IVs antibiotics.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 13:27:29
Query 'PV Query: Please confirm if the subject had an intrauterine system (IUS) placed during this event.' answered with 'No IUD / IVS' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 13:27:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending medical records from hospitalization.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 13:26:42
User opened query 'PV Query: Please clarify what ABS means in relation to ABS IUS in narrative.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:06:39

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject had an intrauterine system (IUS) placed during this event.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:06:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:05:46
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 12:28:59
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 12:28:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 12:28:38
User closed query 'PV Query: Please define the abbreviation IUS.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 12:28:29
Query 'PV Query: Please define the abbreviation IUS.' answered with 'intrauterine system' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:24:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 22:22:47

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:22:26
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 22:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:57
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:03:14
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:41:07
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:41:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:40:55
User opened query 'PV Query: Please define the abbreviation IUS.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:40:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 22:11:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 22:11:01

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'acute salpingitis bilateral presenting with acute severe pelvic pain bilateral. mild nausea requiring hospitalization (11/9-11/12) and ABs IUs. She is currently asymptomatic, recurring at home completing and ABs cycle. Will monitor outcome. Will request hospitalization records for details.'	Jessie Downs (b) (4)	20 Nov 2020 22:11:01
reason for change: Data Entry Error		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 21:59:40
User entered empty.	Jessie Downs (b) (4)	20 Nov 2020 21:59:40



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:59:40

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 21:59:40

**US3172333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 21:59:40

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:36:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:04:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:19:11

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:54:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:54:42
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 18:21:15
User entered 'ADVIL'	Jessie Downs (b) (4)	04 Sep 2020 18:20:35
	(b) (4)	

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 18:20:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 18:20:45
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	04 Sep 2020 18:20:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 18:20:35
User entered empty.	Jessie Downs (b) (4)	04 Sep 2020 18:20:35
	(b) (4)	

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches these Con Med indications during this time frame. If the HEADACHE / LEFT DELTOID PAIN are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE / LEFT DELTOID PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:04:17
Query 'Per DM CLR: Please note that there is no AE that matches these Con Med indications during this time frame. If the HEADACHE / LEFT DELTOID PAIN are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE / LEFT DELTOID PAIN did not meet the AE reporting criteria.' answered with 'did not meet AE criteria ' (Site from DM).	Jessie Downs (b) (4)	16 Oct 2020 21:19:49
	(b) (4)	

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches these Con Med indications during this time frame. If the HEADACHE / LEFT DELTOID PAIN are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE / LEFT DELTOID PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:12:06
User entered 'HEADACHE / LEFT DELTOID PAIN'	Jessie Downs (b) (4)	04 Sep 2020 18:20:35



US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '200'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '26 Aug 2020'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35



US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '0'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	04 Sep 2020 18:20:35

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User closed query 'Per DM CLR: Indication = HEADACHE / LEFT DELTOID PAIN. However, please review and confirm if the response to 'Was this medication taken for solicited event?' should be updated to 'YES' since these are SAR symptoms per protocol and are also recorded in the eDiary within 7 days of SAR reporting. Kindly update if applicable. Otherwise, provide clarification.' (Site from DM). Query 'Per DM CLR: Indication = HEADACHE / LEFT DELTOID PAIN. However, please review and confirm if the response to 'Was this medication taken for solicited event?' should be updated to 'YES' since these are SAR symptoms per protocol and are also recorded in the eDiary within 7 days of SAR reporting. Kindly update if applicable. Otherwise, provide clarification.' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:04:14
Query 'Per DM CLR: Indication = HEADACHE / LEFT DELTOID PAIN. However, please review and confirm if the response to 'Was this medication taken for solicited event?' should be updated to 'YES' since these are SAR symptoms per protocol and are also recorded in the eDiary within 7 days of SAR reporting. Kindly update if applicable. Otherwise, provide clarification.' answered with 'data updated ' (Site from DM).	Jessie Downs (b) (4)	16 Oct 2020 21:20:21
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Oct 2020 21:20:15
	(b) (4)	
User opened query 'Per DM CLR: Indication = HEADACHE / LEFT DELTOID PAIN. However, please review and confirm if the response to 'Was this medication taken for solicited event?' should be updated to 'YES' since these are SAR symptoms per protocol and are also recorded in the eDiary within 7 days of SAR reporting. Kindly update if applicable. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:12:45
User entered 'No (N)'	Jessie Downs (b) (4)	04 Sep 2020 18:20:35
	(b) (4)	

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:20:35

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 18:20:35

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:17:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:17:59
Data point term sent to Coder	System	17 Feb 2021 13:31:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:41:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:41:17
Data point term sent to Coder	System	07 Oct 2020 18:00:08
User entered 'Ibuprofen'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23



US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Headache (Solicited adverse reaction, Not an A/E)'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '200'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'once (ONCE)'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23



US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '25 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '0'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '25 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 17:59:23

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:36:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User entered empty.	System	07 Oct 2020 17:59:23

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User entered empty.	System	07 Oct 2020 17:59:23



US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:31:43
User entered empty.	System	07 Oct 2020 17:59:23

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 13:47:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 13:47:01
Data point term sent to Coder	System	17 Feb 2021 13:31:23
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:50
Data point term sent to Coder	System	20 Nov 2020 22:12:40
User entered 'metronidazole'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'acute salpingitis'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '500'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	20 Nov 2020 22:12:39
	(b) (4)	

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	20 Nov 2020 22:12:39
	(b) (4)	



US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '12 Nov 2020'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:36:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Un-verified.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:23
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:23
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:23
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Un-verified.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:23
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:23
User entered '26 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:23
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 14:40:29
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 14:43:50
' answered with 'Data was updated.' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 14:43:46
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:06:00
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:12:39



US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:36:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
User entered '2'	System	20 Nov 2020 22:12:39

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
User entered '1'	System	20 Nov 2020 22:12:39

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:48:02
User entered '804 (804)'	System	20 Nov 2020 22:12:39

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:17:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:17:59
Data point term sent to Coder	System	17 Feb 2021 13:31:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:26
Data point term sent to Coder	System	20 Nov 2020 22:13:41
User entered 'doxycycline'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'acute salpingitis'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '100'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26



US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '12 Nov 2020'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Un-verified.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:43
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:43
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:43
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26



US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
DataPoint Un-verified.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:43
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:43
User entered '26 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:24:43
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 19:05:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 14:40:47
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 14:44:01
' answered with 'Data was updated.' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Dec 2020 14:43:57
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Nov 2020 22:13:26

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:36:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
User entered '2'	System	20 Nov 2020 22:13:26

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
User entered '1'	System	20 Nov 2020 22:13:26

US3172333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:36:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 00:17:08
User entered '804 (804)'	System	20 Nov 2020 22:13:26

US3172333

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:36:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:42:59
User closed query 'Per ETRTR: According to SAE "Bilateral Acute Salpingitis" page, Concomitant procedure was performed. Please add Procedure performed for such SAE as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:38:19
Query 'Per ETRTR: According to SAE "Bilateral Acute Salpingitis" page, Concomitant procedure was performed. Please add Procedure performed for such SAE as required, thanks.' answered with 'AE was updated. Verified with Sub I and source no concomitant procedure was performed. ' (Site from CRA).	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:59:04
User opened query 'Per ETRTR: According to SAE "Bilateral Acute Salpingitis" page, Concomitant procedure was performed. Please add Procedure performed for such SAE as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 00:42:28
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Sep 2020 20:00:51

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered		
'USA-US118-2020-MRNA-1273-P301000011'	System	23 Nov 2020 23:41:05

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:36:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Mark'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Kutner'	System	23 Nov 2020 23:41:05



**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:36:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'FL'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:32:05
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered 'US'	System	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 12:30:17
Signature has been broken.	System	25 Feb 2021 17:32:34
User entered '3'	System	25 Feb 2021 17:32:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered '2'	System	10 Dec 2020 19:08:16
User entered '1'	System	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered		
'USA-US118-2020-MRNA-1273-P301000011'	System	23 Nov 2020 23:41:05

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:36:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Mark'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Kutner'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'FL'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:32:05
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered 'US'	System	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 12:30:17
Signature has been broken.	System	25 Feb 2021 17:32:34
User entered '3'	System	25 Feb 2021 17:32:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered '2'	System	10 Dec 2020 19:08:16
User entered '1'	System	23 Nov 2020 23:42:07



**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:36:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered '23/Nov/2020 18:42'	System	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:36:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:32:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered		
'USA-US118-2020-MRNA-1273-P301000011'	System	23 Nov 2020 23:41:05

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:36:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Mark'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Kutner'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'FL'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:32:05
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered 'US'	System	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 12:30:17
Signature has been broken.	System	25 Feb 2021 17:32:34
User entered '3'	System	25 Feb 2021 17:32:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered '2'	System	10 Dec 2020 19:08:16
User entered '1'	System	23 Nov 2020 23:42:07

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:36:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered '10/Dec/2020 14:08'	System	10 Dec 2020 19:08:16



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:36:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:32:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 19:08:16

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered		
'USA-US118-2020-MRNA-1273-P301000011'	System	23 Nov 2020 23:41:05

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:36:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Mark'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Kutner'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'FL'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:32:05
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered 'US'	System	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 12:30:17
Signature has been broken.	System	25 Feb 2021 17:32:34
User entered '3'	System	25 Feb 2021 17:32:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered '2'	System	10 Dec 2020 19:08:16
User entered '1'	System	23 Nov 2020 23:42:07

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:36:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
User entered '25/Feb/2021 12:32'	System	25 Feb 2021 17:32:34

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:36:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 17:32:34



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered		
'USA-US118-2020-MRNA-1273-P301000011'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:36:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Yes (Y)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'No (N)'	System	23 Nov 2020 23:41:05



US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:31:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Mark'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'Kutner'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:42:01
User entered 'FL'	System	23 Nov 2020 23:41:05

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:32:05
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered 'US'	System	23 Nov 2020 23:42:07

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Mar 2021 12:30:17
Signature has been broken.	System	25 Feb 2021 17:32:34
User entered '3'	System	25 Feb 2021 17:32:34
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:31:22
	(b) (4)	
User entered '2'	System	10 Dec 2020 19:08:16
User entered '1'	System	23 Nov 2020 23:42:07

**US3172333**

**Folder: SAE USA-US118-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:36:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:59:21
	(b) (4)	
User entered '01/Mar/2021 07:30'	System	01 Mar 2021 12:30:17

US3172333

Folder: SAE USA-US118-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:36:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:59:21
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 12:30:17