

US3002131 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:49:23

All time stamps listed in this document are displayed in GMT

US3002131

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 13:03:19

Generated On: 09 Jun 2021 14:49:23

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[Participant ID](#)

US3002131

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

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US3002131

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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

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US3002131

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 13:03:20

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Date of Informed Consent (*dd MMM yyyy*) 07 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

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

Was this participant screened previously? Yes   
No

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

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 13:03:20

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 13:03:20

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Condition	CARDIOMYOPATHY
Start date (dd MMM yyyy)	UN UNK 2001
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 13:03:20

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Condition	VENTRICULAR FORAMEN (HOLE IN LOWER LEFT VENTRICLE)
Start date (dd MMM yyyy)	UN UNK 1969
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 1971
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1969
Start Year (derived)	1969
Stop Month and Year (derived)	JAN 1971
Stop Year (derived)	1971

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Condition	REPAIR OF VENTRICULAR FORAMEN
Start date (dd MMM yyyy)	UN UNK 1971
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 1971
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1971
Start Year (derived)	1971
Stop Month and Year (derived)	JAN 1971
Stop Year (derived)	1971

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Condition	GRADE 1 SYSTOLIC MURMUR
Start date (dd MMM yyyy)	07 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:45 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:45
Height ( <i>xxx.x</i> )	175 cm
Weight ( <i>xxx.x</i> )	141.1 kg
BMI ( <i>xxx.x</i> )	46.07347 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) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 13:03:20

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Date of assessment (*dd MMM yyyy*) 07 AUG 2020

Is the participant of childbearing potential? Yes   
No

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 13:03:20

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Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 07 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) 13 Feb 2021 13:03:20

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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

---

**Specify**

---

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 13:03:20

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 07 AUG 2020

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

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Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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

What was the participant's randomization number? 142822

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

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

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

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

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

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

Liver Disease Yes  No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 13:03:20

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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) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:45 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:45
Temperature ( <i>xxx.x</i> )	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:53 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 13:53
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

07 AUG 2020

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*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) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Was the pregnancy test performed? Yes   
No

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

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:19 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 13:19

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 07 AUG 2020

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Collection time (*00:00-23:59*) 12:45 (24 HR)

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Collection date and time (derived) 07 AUG 2020 12:45

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US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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Collection date ( <i>dd MMM yyyy</i> )			07 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:51	07 AUG 2020 12:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.9 °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 07 AUG 2020 13:52

PC Open Date & Time 07 AUG 2020 13:39

PC Close Date & Time 07 AUG 2020 16:09

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**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 96.8 °F

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

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

PC Time Stamp 07 AUG 2020 18:06  
PC Open Date & Time 07 AUG 2020 17:04  
PC Close Date & Time 08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 AUG 2020 17:56
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 19:28
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 AUG 2020 18:45
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 AUG 2020 20:51
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 18:11
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 AUG 2020 21:07
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

07 AUG 2020 13:52

PC Open Date & Time

07 AUG 2020 13:39

PC Close Date & Time

07 AUG 2020 16:09

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp 07 AUG 2020 18:07

PC Open Date & Time 07 AUG 2020 17:04

PC Close Date & Time 08 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	08 AUG 2020 17:55
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59



US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

09 AUG 2020 19:27

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

10 AUG 2020 18:44

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

11 AUG 2020 20:51

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

12 AUG 2020 18:10

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

13 AUG 2020 21:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

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

No

Yes

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PC Time stamp	07 AUG 2020 13:53
PC Open Date & Time	07 AUG 2020 13:39
PC Close Date & Time	07 AUG 2020 16:09

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US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**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



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

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

No   
Yes

PC Time stamp	07 AUG 2020 18:07
PC Open Date & Time	07 AUG 2020 17:04
PC Close Date & Time	08 AUG 2020 11:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

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	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 17:56
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

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US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

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	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 19:27
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

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	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 18:44
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

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US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**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



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

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	Yes <input type="checkbox"/>
PC Time stamp	11 AUG 2020 20:52
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

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US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

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	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 18:11
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

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US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

---

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 21:06
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

---

US3002131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3002131

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted?

Yes

No

---

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

21 AUG 2020

---

Please select one status for the follow-up contact

Contact Made

Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---



US3002131

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3002131

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 04 SEP 2020

---

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

---

Folder OID VISIT2

---

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:14 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 08:14
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:42 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 09:42
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	86 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG

US3002131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

04 SEP 2020

---

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

---

US3002131

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 04 SEP 2020

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

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



US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 04 SEP 2020

What was the treatment time? (00:00-23:59) 09:09 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 09:09

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

US3002131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 04 SEP 2020

---

Collection time (*00:00-23:59*) 08:43 (24 HR)

---

Collection date and time (derived) 04 SEP 2020 08:43

---

US3002131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Collection date ( <i>dd MMM yyyy</i> )			04 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:37	04 SEP 2020 08:37
Nasopharyngeal Swab 2	No		

---

US3002131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**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 04 SEP 2020 09:43

PC Open Date & Time 04 SEP 2020 09:29

PC Close Date & Time 04 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.4 °F

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

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

PC Time Stamp	04 SEP 2020 18:20
PC Open Date & Time	04 SEP 2020 12:54
PC Close Date & Time	05 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 SEP 2020 18:56
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 18:29
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 18:52
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 18:29
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 11:49
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 20:35
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

04 SEP 2020 09:44

PC Open Date & Time

04 SEP 2020 09:29

PC Close Date & Time

04 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

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

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

Yes

No

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

Yes

No

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

Please select one response below

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

PC Time Stamp

04 SEP 2020 18:21

PC Open Date & Time

04 SEP 2020 12:54

PC Close Date & Time

05 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

12

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

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR 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

05 SEP 2020 18:55

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	06 SEP 2020 18:30
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 18:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

08 SEP 2020 18:28

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

10 SEP 2020 11:50

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

10 SEP 2020 20:36

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

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

No   
Yes

---

PC Time stamp	04 SEP 2020 09:45
PC Open Date & Time	04 SEP 2020 09:29
PC Close Date & Time	04 SEP 2020 11:59

---

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

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

No   
Yes

---

PC Time stamp	04 SEP 2020 18:22
PC Open Date & Time	04 SEP 2020 12:54
PC Close Date & Time	05 SEP 2020 11:59

---



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

---

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 18:56
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

---

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

---

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 18:31
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

---

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

---

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 18:52
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

---

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

---

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 18:28
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

---



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

---

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 11:50
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

---

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**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

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

---

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 20:36
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

---

US3002131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3002131

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3002131

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3002131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3002131

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 02 OCT 2020

---

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

---

Folder OID VISIT3

---

US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) 02 OCT 2020

Time of assessment (*00:00-23:59*) 08:07 (24 HR)

Vital Signs Date and Time (derived) 02 OCT 2020 08:07

Temperature (*xxx.x*) 37.2 C

Route of measurement Oral   
Axillary   
Other

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

Pulse (*xxx*) 90 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 15 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 130 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 80 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3002131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

02 OCT 2020

---

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

---

US3002131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 02 OCT 2020

---

Collection time (*00:00-23:59*) 08:27 (24 HR)

---

Collection date and time (derived) 02 OCT 2020 08:27

---

US3002131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 64

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

No

Yes

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

No

Yes

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

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

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

Date and time of submission

10 OCT 2020 20:12:06

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59



US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 16 OCT 2020 12:26:53

Patient Cloud Open Date & Time 14 OCT 2020 00:01

Patient Cloud Close Date & Time 18 OCT 2020 23:59

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 21 OCT 2020 00:02:02

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

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

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 04 NOV 2020 01:04:32

Patient Cloud Open Date & Time 04 NOV 2020 00:01

Patient Cloud Close Date & Time 08 NOV 2020 23:59

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 99

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 21:03:58

Patient Cloud Open Date & Time 11 NOV 2020 00:01

Patient Cloud Close Date & Time 15 NOV 2020 23:59

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 106

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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

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Date and time of submission

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Patient Cloud Open Date & Time

18 NOV 2020 00:01

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Patient Cloud Close Date & Time

22 NOV 2020 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission	19 NOV 2020 19:56:55
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 23 NOV 2020 17:50:05

Patient Cloud Open Date & Time 22 NOV 2020 00:01

Patient Cloud Close Date & Time 26 NOV 2020 23:59



US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 29 NOV 2020 17:14:06

Patient Cloud Open Date & Time 29 NOV 2020 00:01

Patient Cloud Close Date & Time 03 DEC 2020 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 DEC 2020 09:16:27
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 DEC 2020 21:29:58
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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 20 DEC 2020 06:17:26

Patient Cloud Open Date & Time 20 DEC 2020 00:01

Patient Cloud Close Date & Time 24 DEC 2020 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 27 DEC 2020 18:12:39

Patient Cloud Open Date & Time 27 DEC 2020 00:01

Patient Cloud Close Date & Time 31 DEC 2020 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 JAN 2021 12:06:19
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 JAN 2021 10:38:49
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 12:00:37
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59



US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 24 JAN 2021 02:09:19

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

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

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

31 JAN 2021 00:09:33

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 03:06:29
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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	15 FEB 2021 14:24:43
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 04:22:47
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 09:05:56
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 17:23:44
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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 14 MAR 2021 00:01:35

Patient Cloud Open Date & Time 14 MAR 2021 00:01

Patient Cloud Close Date & Time 18 MAR 2021 23:59



US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 06:45:57
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 12:18:11
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 04 APR 2021 00:03:32

Patient Cloud Open Date & Time 04 APR 2021 00:01

Patient Cloud Close Date & Time 08 APR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 18:12:13
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 257

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

No

Yes

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

No

Yes

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

Date and time of submission 18 APR 2021 14:01:44

Patient Cloud Open Date & Time 18 APR 2021 00:01

Patient Cloud Close Date & Time 22 APR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 18:42:14
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 01:16:47
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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



**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUN 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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



**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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

Date and time of submission

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06 JUN 2021 00:01

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10 JUN 2021 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

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

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

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Date and time of submission

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13 JUN 2021 00:01

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17 JUN 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 320

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

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

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

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

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

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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

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Date and time of submission

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20 JUN 2021 00:01

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24 JUN 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 327

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3002131**

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

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

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27 JUN 2021 00:01

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01 JUL 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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



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

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

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Date and time of submission

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04 JUL 2021 00:01

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08 JUL 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 341

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

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

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

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

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

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

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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11 JUL 2021 00:01

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15 JUL 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

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

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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18 JUL 2021 00:01

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22 JUL 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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**Generated On: 09 Jun 2021 14:49:23**

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25 JUL 2021 00:01

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29 JUL 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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



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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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05 AUG 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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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? No  Yes

**US3002131**

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

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**Generated On: 09 Jun 2021 14:49:23**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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12 AUG 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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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? No   
Yes

**US3002131**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

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19 AUG 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:49:23

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

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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? No   
Yes

**US3002131**

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

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[Patient Cloud Open Date & Time](#) 22 AUG 2021 00:01

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US3002131

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**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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



**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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



**US3002131**

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

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 10 OCT 2021 00:01

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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

**US3002131**

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

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

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21 OCT 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 446

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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



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

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

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28 OCT 2021 23:59

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US3002131

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

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US3002131

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**TIMEPOINT**

DAY 460

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

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

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

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

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

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

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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18 NOV 2021 23:59

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**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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



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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	21 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 NOV 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 DEC 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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°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



**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3002131**

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

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 26 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 30 DEC 2021 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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

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Date and time of submission

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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



**US3002131**

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**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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°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

**US3002131**

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

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**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3002131**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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



**US3002131**

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**Form: Safety Follow Up Diary**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 FEB 2022 23:59

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US3002131

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#) 24 FEB 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 MAR 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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



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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	03 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°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



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

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14 APR 2022 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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05 MAY 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°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



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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15 MAY 2022 00:01

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19 MAY 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 MAY 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2022 00:01
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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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23 JUN 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

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**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

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US3002131

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**TIMEPOINT**

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes



**US3002131**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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°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



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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

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**TIMEPOINT**

DAY 740

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°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

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

---

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 SEP 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No  Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°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

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**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

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 02 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#) 06 OCT 2022 23:59

---

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

- Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_
- Chills \_\_\_\_\_
- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
- Fatigue \_\_\_\_\_
- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No   
Yes

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

---

US3002131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:49:23

---

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 09:06:09

---

US3002131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 OCT 2020

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3002131

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3002131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 DEC 2020

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3002131

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 JAN 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3002131

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:03:20

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:15:39

Generated On: 09 Jun 2021 14:49:23

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 FEB 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3002131

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:15:39

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3002131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 12:43:49

Generated On: 09 Jun 2021 14:49:23

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 FEB 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID VISIT4

---

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 04:42:26

Generated On: 09 Jun 2021 14:49:23

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) \_\_\_\_\_



US3002131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 12:43:49

Generated On: 09 Jun 2021 14:49:23

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 FEB 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3002131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 12:43:49

Generated On: 09 Jun 2021 14:49:23

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 FEB 2021

---

Collection time (*00:00-23:59*) 08:54 (24 HR)

---

Collection date and time (derived) 19 FEB 2021 08:54

---

US3002131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 12:43:49

Generated On: 09 Jun 2021 14:49:23

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

**US3002131**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

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* \_\_\_\_\_

**US3002131**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3002131

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:49:23

---

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"/>

---

**US3002131**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 14:49:23**

---

Generate Next COVID-19 Assessment

Yes

No

---

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:03:19

Generated On: 09 Jun 2021 14:49:23

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 12 JAN 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID UNBLND\_DECIDE

---



US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 12:43:49

Generated On: 09 Jun 2021 14:49:23

Date of updated informed consent (*dd MMM yyyy*) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes   
No

Under what version of the Protocol was the Participant unblinded? Amendment 5   
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 12 JAN 2021

Participant randomization assignment mRNA-1273   
Placebo

Actual Dose 1 mRNA-1273   
Placebo   
Not Administered

Actual Dose 2 mRNA-1273   
Placebo   
Not Administered

Will participant receive mRNA-1273? Yes   
No

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:03:19

Generated On: 09 Jun 2021 14:49:23

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 12 JAN 2021

---

Collection time (*00:00-23:59*) 08:13 (24 HR)

---

Collection date and time (derived) 12 JAN 2021 08:13

---

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 13:03:19

Generated On: 09 Jun 2021 14:49:23

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 12 JAN 2021

---

Collection time (*00:00 - 23:59*) 08:29

---

Collection Date and Time (derived) 12 JAN 2021 08:29

---

US3002131

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 13:03:19

Generated On: 09 Jun 2021 14:49:23

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

AEID USA-US005-2020-MRNA-1273-P30  
1000012

Adverse event VENOUS THROMBOEMBOLISM

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 07 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 12 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 07 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 12 DEC 2020

Admitted to ICU? Yes   
No   
Unknown

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

---

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   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None False

---

Concomitant Medication True

---

Concomitant Procedure True

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with Sequelae   
Recovering/Resolving   
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

---

PATIENT STATED SHE WAS HAVING SHORTNESS OF BREATH ON 07DEC2020. PATIENT WENT TO THE ER. THEY DID A DOPPLER OF HER RIGHT LEG AND FOUND A DVT AND CT SCAN FOUND PULMONARY EMBOLISMS AND SHE WAS ADMITTED TO HOSPITAL. HGB WAS 6.0 SHE DID NOT HAVE BLOOD TRANSFUSION, BUT RECEIVED IRON VENOFR X 2 DOSES. SUBJECT ALSO REPORTED HEAVY MENSTRUAL BLEEDING OVER SEVERAL MONTHS AND WAS FOUND TO HAVE A LARGE UTERINE FIBROID. SHE HAD UTERINE ABLATION AND THEN WAS STARTED ON XARELTO 20 MG DAILY WHICH SHE CONTINUES.

---

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

---

US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	01 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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EAB) (1725)

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US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

AEID	
Adverse event	ANEMIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

AEID	
Adverse event	UTERINE FIBROID
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)	30 SEP 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)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:30:23

Generated On: 09 Jun 2021 14:49:23

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Mar 2021 12:43:49

Generated On: 09 Jun 2021 14:49:23

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 04:42:26

Generated On: 09 Jun 2021 14:49:23

Name of Medication AMLODIPINE

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 04:42:26

Generated On: 09 Jun 2021 14:49:23

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 01 DEC 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804



US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 04:42:26

Generated On: 09 Jun 2021 14:49:23

Name of Medication IRON SULFATE

Prophylaxis Yes   
No

Indication ANEMIA PROPHYLAXIS

Dose per administration 325

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 04:42:26

Generated On: 09 Jun 2021 14:49:23

---

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*) 11 DEC 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 04:42:26

Generated On: 09 Jun 2021 14:49:23

Name of Medication XARELTO

Prophylaxis Yes   
No

Indication VENOUS THROMBOEMBOLISM PREVENTION

Dose per administration 20

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

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EAB) (1725)

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US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 04:42:26

Generated On: 09 Jun 2021 14:49:23

---

	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) 12 DEC 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

---

US3002131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Mar 2021 12:43:49

Generated On: 09 Jun 2021 14:49:23

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3002131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Mar 2021 19:57:11

Generated On: 09 Jun 2021 14:49:23

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
13 JAN 2021	UTERINE ABLATION	Adverse Event	
07 DEC 2020	DOPPLER OF LEFT LEG	Adverse Event	

US3002131

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:23

---

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

---

US3002131

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:49:23

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



US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 11:48:52

Generated On: 09 Jun 2021 14:49:23

SAEID	USA-US005-2020-MRNA-1273-P30 1000012
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 11:48:52

Generated On: 09 Jun 2021 14:49:23

SAEID	USA-US005-2020-MRNA-1273-P301000012
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/DEC/2020 17:18
<b>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.</b>	True

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 11:48:52

Generated On: 09 Jun 2021 14:49:23

SAEID	USA-US005-2020-MRNA-1273-P301000012
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/JAN/2021 11:40
<b>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.</b>	True

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 11:48:52

Generated On: 09 Jun 2021 14:49:23

SAEID	USA-US005-2020-MRNA-1273-P301000012
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 12:05
<b>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.</b>	True

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 01 May 2021 11:48:52

Generated On: 09 Jun 2021 14:49:23

SAEID	USA-US005-2020-MRNA-1273-P301000012
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/MAR/2021 13:24
<b>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.</b>	True

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 01 May 2021 11:48:52

Generated On: 09 Jun 2021 14:49:23

SAEID	USA-US005-2020-MRNA-1273-P30 1000012
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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/APR/2021 12:38
<b>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.</b>	True

Audit

US3002131 (Prod: Meridian Clinical Research)

**US3002131**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:49:23**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'US3002131'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 17:34:36



US3002131

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:25:47
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:27

US3002131

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:25:47
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 17:34:36

**US3002131**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:25:47
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:27

**US3002131**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'SCRN'	System	10 Aug 2020 15:08:27

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 17:34:37

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '51'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'YEARS'	System	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '51'	System	07 Aug 2020 18:25:47



US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42



US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:23

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:08:42

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:25:47
	(b) (4)	

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Aug 2020'	System	07 Aug 2020 18:25:47

**US3002131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:49:23**

[Year of Informed Consent \(derived\)](#)

---

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '2020'	System	07 Aug 2020 18:25:47

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Amendment 1 (1)'	Tiffany Nemecek (b) (4)	07 Aug 2020 18:25:47

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:25:47



US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:25:47
	(b) (4)	

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:25:47
	(b) (4)	

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:25:47

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 17:34:36

US3002131

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '1'	System	07 Aug 2020 18:25:54

US3002131

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:49:23

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:25:54

US3002131

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:49:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:36

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Per DM CLR: Please specify the type of CARDIOMYOPATHY, if known. 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)	11 Sep 2020 07:02:14
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 15:35:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 15:35:40
Data point term sent to Coder	System	10 Sep 2020 15:34:21
Query 'Per DM CLR: Please specify the type of CARDIOMYOPATHY, if known. 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 'Unknown. No meds.' (Site from DM).	Brandon Essink (b) (4)	10 Sep 2020 15:33:40
Coding entries removed.	Brandon Essink (b) (4)	10 Sep 2020 15:33:29
User entered 'CARDIOMYOPATHY' reason for change: Per Query Resolution	Brandon Essink (b) (4)	10 Sep 2020 15:33:29
User opened query 'Per DM CLR: Please specify the type of CARDIOMYOPATHY, if known. 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)	01 Sep 2020 23:38:58
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 23:31:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 23:31:28
Data point term sent to Coder	System	10 Aug 2020 15:10:23



US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

[Condition](#)

Audit	User	Time (GMT)
User entered 'Cardio myopathy'	(b) (4), (b) (6)	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Jan 2001'	System	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '2001'	System	10 Aug 2020 15:09:56



US3002131

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Jan 2013'	System	10 Aug 2020 15:09:56

**US3002131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '2013'	System	10 Aug 2020 15:09:56

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Ventricular septal defect, LLT: Ventricular septal defect - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 09:37:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 09:37:21
Data point term sent to Coder	System	02 Oct 2020 15:44:06
User closed query 'DM-CODING: Please clarify the diagnosis more precisely, verify location/type e.g. it was Ventricular septal defect etc.. Please update the diagnosis in accordance with your answer.' (Site from System).	System	02 Oct 2020 15:43:09
Query 'DM-CODING: Please clarify the diagnosis more precisely, verify location/type e.g. it was Ventricular septal defect etc.. Please update the diagnosis in accordance with your answer.' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 15:43:09
Data point term sent to Coder	System	02 Oct 2020 15:43:05
User entered 'VENTRICULAR FORAMEN (hole in lower left ventricle)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 15:43:01
User opened query 'DM-CODING: Please clarify the diagnosis more precisely, verify location/type e.g. it was Ventricular septal defect etc.. Please update the diagnosis in accordance with your answer.' (Site from System).	Coder Import (b) (4)	17 Sep 2020 14:35:32
Data point term sent to Coder	System	10 Aug 2020 15:10:25
User entered 'Ventricular foramen'	(b) (4), (b) (6)	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Per CDM: it appears DOB is (b) (6) 1969 and Condition is recorded an UN UNK 1969. Please confirm the Condition start date is not prior to participant's DOB.' (Site from DM).	(b) (4)	18 Aug 2020 12:53:34
Query 'Per CDM: it appears DOB is (b) (6) 1969 and Condition is recorded an UN UNK 1969. Please confirm the Condition start date is not prior to participant's DOB.' answered with 'Condition start date is not prior to DOB.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 14:26:25
User opened query 'Per CDM: it appears DOB is (b) (6) 1969 and Condition is recorded an UN UNK 1969. Please confirm the Condition start date is not prior to participant's DOB.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 09:22:25
Query 'Start date is prior to Date of Birth. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 09:22:00
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	10 Aug 2020 15:10:17
User entered 'un UNK 1969'	(b) (4), (b) (6)	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:10:17

**US3002131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'un UNK 1971'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:10:17



US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered (b) (6) 1969'	System	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '1969'	System	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Jan 1971'	System	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:23

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '1971'	System	10 Aug 2020 15:10:17

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User coded data point as SOC: Surgical and medical procedures, HLG: Cardiac therapeutic procedures, HLT: Congenital cardiovascular anomaly therapeutic procedures, PT: Ventricular septal defect repair, LLT: Ventricular septal defect repair - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 12:25:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 12:25:03
Data point term sent to Coder	System	10 Aug 2020 15:11:27
User entered 'Repair of ventricular foramen'	(b) (4), (b) (6)	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'un UNK 1971'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:08



US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'un UNK 1971'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Jan 1971'	System	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '1971'	System	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Jan 1971'	System	10 Aug 2020 15:11:08

**US3002131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '1971'	System	10 Aug 2020 15:11:08

US3002131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 15:12:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 15:12:16
Data point term sent to Coder	System	10 Aug 2020 15:11:29
User entered 'Obesity'	(b) (4), (b) (6)	10 Aug 2020 15:11:22

US3002131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:22



US3002131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:22

**US3002131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:22

US3002131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:23

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:22

US3002131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:11:22

US3002131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Jan 1998'	System	10 Aug 2020 15:11:22

**US3002131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '1998'	System	10 Aug 2020 15:11:22

US3002131

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered empty.	System	10 Aug 2020 15:11:22

**US3002131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered empty.	System	10 Aug 2020 15:11:22



US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User coded data point as SOC: Investigations, HLGTT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Systolic murmur - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Aug 2020 09:19:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:19:12
Data point term sent to Coder	System	11 Aug 2020 18:34:35
User entered 'Grade 1 Systolic murmur'	Tiffany Nemecek (b) (4) (b) (4)	11 Aug 2020 18:33:51

US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. Please review, verify dates and update as per CCGs page 22.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 08:09:08
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. Please review, verify dates and update as per CCGs page 22.' answered with "This is correct. During PE this was noted" (Site from DM).	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 01:39:43
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. Please review, verify dates and update as per CCGs page 22.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 10:28:18
User entered '07 Aug 2020'	Tiffany Nemecek (b) (4) (b) (4)	11 Aug 2020 18:33:51

US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 18:33:51

US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	11 Aug 2020 18:34:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Tiffany Nemecek (b) (4)	11 Aug 2020 18:34:07
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	11 Aug 2020 18:33:51
User entered 'No (N)'	Tiffany Nemecek (b) (4)	11 Aug 2020 18:33:51

US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 18:33:51
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) Tiffany Nemecek (b) (4)	11 Aug 2020 18:33:51

US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'Aug 2020'	System	11 Aug 2020 18:33:51

**US3002131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:49:23**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '2020'	System	11 Aug 2020 18:33:51



US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered empty.	System	11 Aug 2020 18:33:51

US3002131

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:23

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered empty.	System	11 Aug 2020 18:33:51

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '11:45'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered '07 Aug 2020 11:45'	System	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '175' cm	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:12:39
DataPoint set to visible.	System	07 Aug 2020 18:25:54

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '141.1' kg	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:12:39
DataPoint set to visible.	System	07 Aug 2020 18:25:54



US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
Amendment Manager: User entered '46.07347'	System	16 Sep 2020 23:47:41
User entered '46.1'	System	10 Aug 2020 15:12:39
DataPoint set to visible.	System	07 Aug 2020 18:25:54

**US3002131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'kg/m2'	System	10 Aug 2020 15:12:39
DataPoint set to visible.	System	07 Aug 2020 18:25:54

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:56:54
User entered '36.9' C	(b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:56:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:56:54
User entered '71'	(b) (4), (b) (6)	10 Aug 2020 15:12:39

**US3002131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'bpm'	System	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:56:54
User entered '16'	(b) (4), (b) (6)	10 Aug 2020 15:12:39



US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'breaths/min'	System	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:56:54
User entered '148'	(b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'mmHg'	System	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:56:54
User entered '76'	(b) (4), (b) (6)	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered 'mmHg'	System	10 Aug 2020 15:12:39

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36

US3002131

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36

US3002131

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:12:48



US3002131

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 04:54:26
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 15:59:01
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 15:12:48

US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12

US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12

US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12

US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12

US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12

US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12

US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12



US3002131

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:23

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:12

US3002131

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:26

**US3002131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:49:23**

*Date of test (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:26

US3002131

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:26

US3002131

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:26

US3002131

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:12:50
Query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 18:17:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 18:17:54
User opened query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:21:53
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 15:13:26

**US3002131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:26

US3002131

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:26



US3002131

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User entered empty.	System	10 Aug 2020 15:13:26

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

**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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

**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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

**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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04



US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

**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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

**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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04



US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

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)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:36
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:09:04

US3002131

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:40

US3002131

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:40



US3002131

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:40

**US3002131**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'VISIT1'	System	10 Aug 2020 15:13:40

US3002131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:23

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 17:59:24

US3002131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:23

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:55:07
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:55:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 17:59:24
User entered '142822' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 17:59:24

US3002131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:23

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 17:59:24

US3002131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:23

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)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:53

US3002131

Folder: Visit 1 Day 1

Form: Randomization

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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)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:23

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:53



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Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:53

**US3002131**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:49:23**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:13:53

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:57:08
User entered '175' cm	(b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:57:08
User entered '141.1' kg	(b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:57:08
User entered '175' cm	(b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:57:08
User entered '141.1' kg	(b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16



US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '11:45'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered '07 Aug 2020 11:45'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '71'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'bpm'	System	10 Aug 2020 15:15:16



US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'breaths/min'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '148'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'mmHg'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '76'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'mmHg'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:57:08
User entered '175' cm	(b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:57:08
User entered '141.1' kg	(b) (4), (b) (6)	10 Aug 2020 15:15:16



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 09:08:13
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Data correct as entered. ' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 15:15:27
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 15:15:16
User entered '13:53'	(b) (4), (b) (6)	10 Aug 2020 15:15:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered '07 Aug 2020 13:53'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '80' reason for change: Data Entry Error	(b) (4)	10 Aug 2020 15:15:30
User entered '78'	(b) (4), (b) (6)	10 Aug 2020 15:15:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'bpm'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'breaths/min'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '148'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'mmHg'	System	10 Aug 2020 15:15:16

US3002131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '90'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'mmHg'	System	10 Aug 2020 15:15:16



US3002131

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:39

US3002131

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:39

US3002131

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Per CDM: Please consider entering "No" for this field and remove Date of test, Test performed and Result as screening and VID1 have occurred on the same day.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:12:55
' (Site from DM). Query 'Per CDM: Please consider entering "No" for this field and remove Date of test, Test performed and Result as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	09 Oct 2020 18:18:20
' answered with 'updated' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 18:18:14
User opened query 'Per CDM: Please consider entering "No" for this field and remove Date of test, Test performed and Result as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	08 Oct 2020 12:21:25
' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 15:15:50

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty; reason for change Data Entry Error	(b) (4)	09 Oct 2020 18:18:14
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 15:15:50

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty; reason for change Data Entry Error	(b) (4)	09 Oct 2020 18:18:14
User entered 'Urine (URINE)'	(b) (4), (b) (6)	10 Aug 2020 15:15:50

US3002131

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty; reason for change Data Entry Error	(b) (4)	09 Oct 2020 18:18:14
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	10 Aug 2020 15:15:50

US3002131

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:12:57
Query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 18:18:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 18:18:14
User opened query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:21:40
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 15:15:50

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:50



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:15:50

US3002131

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered empty.	System	10 Aug 2020 15:15:50

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:26:25
	(b) (4)	

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:26:25
	(b) (4)	

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

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)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:26:25
	(b) (4)	

**US3002131**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:49:23**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 18:26:25

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:26:25
	(b) (4)	

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '13:19'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:26:25
	(b) (4)	



US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered '07 Aug 2020 13:19'	System	07 Aug 2020 18:26:25

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Nemecek (b) (4)	07 Aug 2020 18:26:25

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'ONCE'	System	07 Aug 2020 18:26:25

US3002131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 18:26:25

US3002131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:07

US3002131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:07

US3002131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '12:45'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:07

US3002131

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered '07 Aug 2020 12:45'	System	10 Aug 2020 15:16:07



US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:49:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:23

US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Aug 2020 15:16:23

US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:23

US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '12:51'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:23

**US3002131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered '07 Aug 2020 12:51'	System	10 Aug 2020 15:16:23

US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Aug 2020 15:16:23

US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:23

US3002131

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:23



**US3002131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered empty.	System	10 Aug 2020 15:16:23

US3002131

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:28

US3002131

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered '1'	System	10 Aug 2020 15:16:28

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:51:55', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '8236f034-9aea-4f33-941f-ee0d77a18b04' User entered 'Yes (Y)'	System	07 Aug 2020 18:52:20
	System	07 Aug 2020 18:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '8236f034-9aea-4f33-941f-ee0d77a18b04'	System	07 Aug 2020 18:52:20
User entered '97.9'	System	07 Aug 2020 18:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:08', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '8236f034-9aea-4f33-941f-ee0d77a18b04'	System	07 Aug 2020 18:52:20
User entered 'No (N)'	System	07 Aug 2020 18:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:16', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '8236f034-9aea-4f33-941f-ee0d77a18b04' User entered '07 Aug 2020 13:52'	System	07 Aug 2020 18:52:20
	System	07 Aug 2020 18:52:20



US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 13:39'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 16:09'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:06:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '873f22c4-673c-4732-9e94-95cc7949e1cd' User entered 'Yes (Y)'	System	07 Aug 2020 23:06:44
	System	07 Aug 2020 23:06:44

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:06:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '873f22c4-673c-4732-9e94-95cc7949e1cd' User entered '96.8'	System	07 Aug 2020 23:06:44
	System	07 Aug 2020 23:06:44

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:06:36', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '873f22c4-673c-4732-9e94-95cc7949e1cd' User entered 'No (N)'	System	07 Aug 2020 23:06:44
	System	07 Aug 2020 23:06:44

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:06:40', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '873f22c4-673c-4732-9e94-95cc7949e1cd' User entered '07 Aug 2020 18:06'	System	07 Aug 2020 23:06:44
	System	07 Aug 2020 23:06:44

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 17:04'	System	07 Aug 2020 18:26:25



US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 2'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:04', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c6a122a5-d9c2-4f5a-9bb7-d4042b016a8f' User entered 'Yes (Y)'	System	08 Aug 2020 22:56:24
	System	08 Aug 2020 22:56:24

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:09', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c6a122a5-d9c2-4f5a-9bb7-d4042b016a8f' User entered '96.8'	System	08 Aug 2020 22:56:24
	System	08 Aug 2020 22:56:24

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c6a122a5-d9c2-4f5a-9bb7-d4042b016a8f' User entered 'No (N)'	System	08 Aug 2020 22:56:24
	System	08 Aug 2020 22:56:24

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:22', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c6a122a5-d9c2-4f5a-9bb7-d4042b016a8f' User entered '08 Aug 2020 17:56'	System	08 Aug 2020 22:56:24
	System	08 Aug 2020 22:56:24

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:26:25



US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 3'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f0a99d2c-d98f-462f-8306-b3197710ff95'	System	10 Aug 2020 00:28:19
User entered 'Yes (Y)'	System	10 Aug 2020 00:28:19

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:50', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f0a99d2c-d98f-462f-8306-b3197710ff95' User entered '97.3'	System	10 Aug 2020 00:28:19
	System	10 Aug 2020 00:28:19

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:53', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f0a99d2c-d98f-462f-8306-b3197710ff95'	System	10 Aug 2020 00:28:19
User entered 'No (N)'	System	10 Aug 2020 00:28:19

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:28:18', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f0a99d2c-d98f-462f-8306-b3197710ff95' User entered '09 Aug 2020 19:28'	System	10 Aug 2020 00:28:19
	System	10 Aug 2020 00:28:19

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 4'	System	07 Aug 2020 18:26:25



US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:52', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '99da370e-dc18-4bb9-8054-5bbfec082155' User entered 'Yes (Y)'	System	10 Aug 2020 23:45:13
	System	10 Aug 2020 23:45:13

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:59', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '99da370e-dc18-4bb9-8054-5bbfec082155' User entered '98.5'	System	10 Aug 2020 23:45:13
	System	10 Aug 2020 23:45:13

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:45:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '99da370e-dc18-4bb9-8054-5bbfec082155'	System	10 Aug 2020 23:45:13
User entered 'No (N)'	System	10 Aug 2020 23:45:13

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:45:10', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '99da370e-dc18-4bb9-8054-5bbfec082155' User entered '10 Aug 2020 18:45'	System	10 Aug 2020 23:45:13
	System	10 Aug 2020 23:45:13

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 5'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:01', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'babd0f60-09ce-492b-afdc-a32ed1ddff27'	System	12 Aug 2020 01:51:40
User entered 'Yes (Y)'	System	12 Aug 2020 01:51:40



US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'babd0f60-09ce-492b-afdc-a32ed1ddff27'	System	12 Aug 2020 01:51:40
User entered '98.0'	System	12 Aug 2020 01:51:40

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:09', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'babd0f60-09ce-492b-afdc-a32ed1ddff27'	System	12 Aug 2020 01:51:40
User entered 'No (N)'	System	12 Aug 2020 01:51:40

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:36', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'babd0f60-09ce-492b-afdc-a32ed1ddff27'	System	12 Aug 2020 01:51:40
User entered '11 Aug 2020 20:51'	System	12 Aug 2020 01:51:40

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 6'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:12', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6619f7f2-bb01-460f-945e-d5c21f446993'	System	12 Aug 2020 23:11:31
User entered 'Yes (Y)'	System	12 Aug 2020 23:11:31

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:16', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6619f7f2-bb01-460f-945e-d5c21f446993' User entered '97.8'	System	12 Aug 2020 23:11:31
	System	12 Aug 2020 23:11:31



US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:23', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6619f7f2-bb01-460f-945e-d5c21f446993'	System	12 Aug 2020 23:11:31
User entered 'No (N)'	System	12 Aug 2020 23:11:31

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6619f7f2-bb01-460f-945e-d5c21f446993' User entered '12 Aug 2020 18:11'	System	12 Aug 2020 23:11:31
	System	12 Aug 2020 23:11:31

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 7'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:49', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7661f74b-6662-490d-b16e-a26b2ea6c6e5' User entered 'Yes (Y)'	System	14 Aug 2020 02:07:16
	System	14 Aug 2020 02:07:16

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:54', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7661f74b-6662-490d-b16e-a26b2ea6c6e5' User entered '97.3'	System	14 Aug 2020 02:07:16
	System	14 Aug 2020 02:07:16

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:07:12', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7661f74b-6662-490d-b16e-a26b2ea6c6e5' User entered 'No (N)'	System	14 Aug 2020 02:07:16
	System	14 Aug 2020 02:07:16



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:07:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7661f74b-6662-490d-b16e-a26b2ea6c6e5'	System	14 Aug 2020 02:07:16
User entered '13 Aug 2020 21:07'	System	14 Aug 2020 02:07:16

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ca8d1519-09c5-4a3d-8460-11fce2786eea' User entered 'None (1)'	System	07 Aug 2020 18:53:00
	System	07 Aug 2020 18:53:00

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ca8d1519-09c5-4a3d-8460-11fce2786eea' User entered 'No (N)'	System	07 Aug 2020 18:53:00
	System	07 Aug 2020 18:53:00

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ca8d1519-09c5-4a3d-8460-11fce2786eea' User entered 'No (N)'	System	07 Aug 2020 18:53:00
	System	07 Aug 2020 18:53:00

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:53', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ca8d1519-09c5-4a3d-8460-11fce2786eea'	System	07 Aug 2020 18:53:00
User entered 'None (1)'	System	07 Aug 2020 18:53:00



US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:52:56', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ca8d1519-09c5-4a3d-8460-11fce2786eea' User entered '07 Aug 2020 13:52'	System	07 Aug 2020 18:53:00
	System	07 Aug 2020 18:53:00

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 13:39'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 16:09'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ebe3889d-89d3-4da3-8d53-d9af9a5d84f2'	System	07 Aug 2020 23:07:30
User entered 'None (1)'	System	07 Aug 2020 23:07:30

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:17', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ebe3889d-89d3-4da3-8d53-d9af9a5d84f2'	System	07 Aug 2020 23:07:30
User entered 'No (N)'	System	07 Aug 2020 23:07:30

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ebe3889d-89d3-4da3-8d53-d9af9a5d84f2'	System	07 Aug 2020 23:07:30
User entered 'No (N)'	System	07 Aug 2020 23:07:30

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:25', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ebe3889d-89d3-4da3-8d53-d9af9a5d84f2'	System	07 Aug 2020 23:07:30
User entered 'None (1)'	System	07 Aug 2020 23:07:30



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ebe3889d-89d3-4da3-8d53-d9af9a5d84f2' User entered '07 Aug 2020 18:07'	System	07 Aug 2020 23:07:30
	System	07 Aug 2020 23:07:30

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 17:04'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 2'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:55:17', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '81932cd9-502d-460a-bc37-a6820fe021a8'	System	08 Aug 2020 22:55:59
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 22:55:59

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

**Is there any REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:55:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '81932cd9-502d-460a-bc37-a6820fe021a8' User entered 'No (N)'	System	08 Aug 2020 22:55:59
	System	08 Aug 2020 22:55:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:55:28', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '81932cd9-502d-460a-bc37-a6820fe021a8' User entered 'No (N)'	System	08 Aug 2020 22:55:59
	System	08 Aug 2020 22:55:59

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:55:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '81932cd9-502d-460a-bc37-a6820fe021a8'	System	08 Aug 2020 22:55:59
User entered 'None (1)'	System	08 Aug 2020 22:55:59



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:55:57', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '81932cd9-502d-460a-bc37-a6820fe021a8' User entered '08 Aug 2020 17:55'	System	08 Aug 2020 22:55:59
	System	08 Aug 2020 22:55:59

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 3'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:26:53', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '046f47d5-2f19-410b-9a72-c8a81b1419db'	System	10 Aug 2020 00:27:08
User entered 'None (1)'	System	10 Aug 2020 00:27:08

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:26:56', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '046f47d5-2f19-410b-9a72-c8a81b1419db' User entered 'No (N)'	System	10 Aug 2020 00:27:08
	System	10 Aug 2020 00:27:08

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:26:59', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '046f47d5-2f19-410b-9a72-c8a81b1419db' User entered 'No (N)'	System	10 Aug 2020 00:27:08
	System	10 Aug 2020 00:27:08

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:01', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '046f47d5-2f19-410b-9a72-c8a81b1419db'	System	10 Aug 2020 00:27:08
User entered 'None (1)'	System	10 Aug 2020 00:27:08



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '046f47d5-2f19-410b-9a72-c8a81b1419db' User entered '09 Aug 2020 19:27'	System	10 Aug 2020 00:27:08
	System	10 Aug 2020 00:27:08

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 4'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:43:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f54a5b0c-3639-4f2f-ae5d-fd2ad227cb21'	System	10 Aug 2020 23:44:11
User entered 'None (1)'	System	10 Aug 2020 23:44:11

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f54a5b0c-3639-4f2f-ae5d-fd2ad227cb21'	System	10 Aug 2020 23:44:11
User entered 'No (N)'	System	10 Aug 2020 23:44:11

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:05', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f54a5b0c-3639-4f2f-ae5d-fd2ad227cb21'	System	10 Aug 2020 23:44:11
User entered 'No (N)'	System	10 Aug 2020 23:44:11

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:07', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f54a5b0c-3639-4f2f-ae5d-fd2ad227cb21'	System	10 Aug 2020 23:44:11
User entered 'None (1)'	System	10 Aug 2020 23:44:11



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:09', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'f54a5b0c-3639-4f2f-ae5d-fd2ad227cb21'	System	10 Aug 2020 23:44:11
User entered '10 Aug 2020 18:44'	System	10 Aug 2020 23:44:11

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 5'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1b019a89-6330-48ec-b5c7-1aee93ff80f9'	System	12 Aug 2020 01:51:58
User entered 'None (1)'	System	12 Aug 2020 01:51:58

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

**Is there any REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:44', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1b019a89-6330-48ec-b5c7-1aee93ff80f9'	System	12 Aug 2020 01:51:58
User entered 'No (N)'	System	12 Aug 2020 01:51:58

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:47', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1b019a89-6330-48ec-b5c7-1aee93ff80f9'	System	12 Aug 2020 01:51:58
User entered 'No (N)'	System	12 Aug 2020 01:51:58

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:50', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1b019a89-6330-48ec-b5c7-1aee93ff80f9'	System	12 Aug 2020 01:51:58
User entered 'None (1)'	System	12 Aug 2020 01:51:58



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:51:55', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1b019a89-6330-48ec-b5c7-1aee93ff80f9' User entered '11 Aug 2020 20:51'	System	12 Aug 2020 01:51:58
	System	12 Aug 2020 01:51:58

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 6'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:04', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '4b9c82a0-f895-472f-b7d4-23fb22a57d20'	System	12 Aug 2020 23:10:33
User entered 'None (1)'	System	12 Aug 2020 23:10:33

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '4b9c82a0-f895-472f-b7d4-23fb22a57d20' User entered 'No (N)'	System	12 Aug 2020 23:10:33
	System	12 Aug 2020 23:10:33

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '4b9c82a0-f895-472f-b7d4-23fb22a57d20' User entered 'No (N)'	System	12 Aug 2020 23:10:33
	System	12 Aug 2020 23:10:33

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:23', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '4b9c82a0-f895-472f-b7d4-23fb22a57d20'	System	12 Aug 2020 23:10:33
User entered 'None (1)'	System	12 Aug 2020 23:10:33



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '4b9c82a0-f895-472f-b7d4-23fb22a57d20' User entered '12 Aug 2020 18:10'	System	12 Aug 2020 23:10:33
	System	12 Aug 2020 23:10:33

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 7'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:05:57', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6deb1a69-90c2-4e2c-ba04-7b99393dd656'	System	14 Aug 2020 02:06:09
User entered 'None (1)'	System	14 Aug 2020 02:06:09

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:00', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6deb1a69-90c2-4e2c-ba04-7b99393dd656' User entered 'No (N)'	System	14 Aug 2020 02:06:09
	System	14 Aug 2020 02:06:09

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6deb1a69-90c2-4e2c-ba04-7b99393dd656' User entered 'No (N)'	System	14 Aug 2020 02:06:09
	System	14 Aug 2020 02:06:09

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:04', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6deb1a69-90c2-4e2c-ba04-7b99393dd656'	System	14 Aug 2020 02:06:09
User entered 'None (1)'	System	14 Aug 2020 02:06:09



US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6deb1a69-90c2-4e2c-ba04-7b99393dd656' User entered '13 Aug 2020 21:06'	System	14 Aug 2020 02:06:09
	System	14 Aug 2020 02:06:09

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:09', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered 'None (0)'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered 'None (0)'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:16', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered 'None (0)'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:18', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered 'None (0)'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:20', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered 'None (0)'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:22', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered 'None (0)'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:28', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered 'No (N)'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T13:53:31', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1f39a615-c020-4392-8e95-20bb5a30106e' User entered '07 Aug 2020 13:53'	System	07 Aug 2020 18:53:33
	System	07 Aug 2020 18:53:33

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 13:39'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 16:09'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered 'None (0)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:34', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered 'None (0)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:37', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered 'None (0)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered 'None (0)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered 'None (0)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:44', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered 'None (0)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:48', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered 'No (N)'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-07T18:07:51', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'eb1d7631-5b10-425d-a156-f89b216755ee' User entered '07 Aug 2020 18:07'	System	07 Aug 2020 23:07:53
	System	07 Aug 2020 23:07:53

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Aug 2020 17:04'	System	07 Aug 2020 18:26:25



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 2'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:28', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249' User entered 'None (0)'	System	08 Aug 2020 22:56:59
	System	08 Aug 2020 22:56:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:34', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249' User entered 'None (0)'	System	08 Aug 2020 22:56:59
	System	08 Aug 2020 22:56:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:38', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249' User entered 'None (0)'	System	08 Aug 2020 22:56:59
	System	08 Aug 2020 22:56:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:45', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249' User entered 'None (0)'	System	08 Aug 2020 22:56:59
	System	08 Aug 2020 22:56:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:50', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249' User entered 'None (0)'	System	08 Aug 2020 22:56:59
	System	08 Aug 2020 22:56:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:52', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249' User entered 'None (0)'	System	08 Aug 2020 22:56:59
	System	08 Aug 2020 22:56:59



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:55', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249'	System	08 Aug 2020 22:56:59
User entered 'No (N)'	System	08 Aug 2020 22:56:59

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-08T17:56:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '67a44367-a7e6-4ef5-b3ba-888d0d4dc249'	System	08 Aug 2020 22:56:59
User entered '08 Aug 2020 17:56'	System	08 Aug 2020 22:56:59

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 3'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1' User entered 'None (0)'	System	10 Aug 2020 00:27:35
	System	10 Aug 2020 00:27:35

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:17', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1' User entered 'None (0)'	System	10 Aug 2020 00:27:35
	System	10 Aug 2020 00:27:35

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1' User entered 'None (0)'	System	10 Aug 2020 00:27:35
	System	10 Aug 2020 00:27:35



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:22', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1' User entered 'None (0)'	System	10 Aug 2020 00:27:35
	System	10 Aug 2020 00:27:35

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:24', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1' User entered 'None (0)'	System	10 Aug 2020 00:27:35
	System	10 Aug 2020 00:27:35

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:26', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1' User entered 'None (0)'	System	10 Aug 2020 00:27:35
	System	10 Aug 2020 00:27:35

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1'	System	10 Aug 2020 00:27:35
User entered 'No (N)'	System	10 Aug 2020 00:27:35

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-09T19:27:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c66e8565-21b2-4bf2-b5cc-d42e034a06c1' User entered '09 Aug 2020 19:27'	System	10 Aug 2020 00:27:35
	System	10 Aug 2020 00:27:35

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 4'	System	07 Aug 2020 18:26:25



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:13', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098'	System	10 Aug 2020 23:44:33
User entered 'None (0)'	System	10 Aug 2020 23:44:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:20', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098'	System	10 Aug 2020 23:44:33
User entered 'None (0)'	System	10 Aug 2020 23:44:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:22', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098'	System	10 Aug 2020 23:44:33
User entered 'None (0)'	System	10 Aug 2020 23:44:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:23', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098' User entered 'None (0)'	System	10 Aug 2020 23:44:33
	System	10 Aug 2020 23:44:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:25', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098'	System	10 Aug 2020 23:44:33
User entered 'None (0)'	System	10 Aug 2020 23:44:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098'	System	10 Aug 2020 23:44:33
User entered 'None (0)'	System	10 Aug 2020 23:44:33

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098'	System	10 Aug 2020 23:44:33
User entered 'No (N)'	System	10 Aug 2020 23:44:33

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-10T18:44:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a607956f-7d86-49d3-b115-7005d848a098' User entered '10 Aug 2020 18:44'	System	10 Aug 2020 23:44:33
	System	10 Aug 2020 23:44:33



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 5'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:00', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered 'None (0)'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered 'None (0)'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:05', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered 'None (0)'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:07', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered 'None (0)'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:09', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered 'None (0)'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:11', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered 'None (0)'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered 'No (N)'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-11T20:52:17', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2dac1aca-85bf-4389-a1d2-03f8a0c1c90f' User entered '11 Aug 2020 20:52'	System	12 Aug 2020 01:52:20
	System	12 Aug 2020 01:52:20

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 6'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:36', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered 'None (0)'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered 'None (0)'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:43', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered 'None (0)'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:10:46', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered 'None (0)'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:00', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered 'None (0)'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered 'None (0)'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:05', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered 'No (N)'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-12T18:11:07', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '2c4e6619-bdd3-4a98-9f69-5b885c61895c' User entered '12 Aug 2020 18:11'	System	12 Aug 2020 23:11:09
	System	12 Aug 2020 23:11:09

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:26:25



US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 7'	System	07 Aug 2020 18:26:25

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:21', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered 'None (0)'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:23', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered 'None (0)'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:25', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered 'None (0)'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered 'None (0)'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:31', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered 'None (0)'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered 'None (0)'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45

US3002131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:38', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered 'No (N)'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45



**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-08-13T21:06:40', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ee6f3495-1625-47b2-86b9-a5aa2a79c47e' User entered '13 Aug 2020 21:06'	System	14 Aug 2020 02:06:45
	System	14 Aug 2020 02:06:45

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:26:52

**US3002131**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:26:52

US3002131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:26:52

US3002131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:26:52

**US3002131**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:27:01



**US3002131**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered 'I'	System	17 Aug 2020 14:27:01

**US3002131**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:57:51

**US3002131**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:57:51

US3002131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:57:51

US3002131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:57:51

US3002131

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	04 Sep 2020 14:33:14

**US3002131**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:45
User entered '1'	System	04 Sep 2020 14:33:14

US3002131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:40
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:34



US3002131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:40
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:34

US3002131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:40
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:34

US3002131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:40
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:34

US3002131

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:40
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4) (b) (4)	04 Sep 2020 14:33:46

**US3002131**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:40
User entered '1'	System	04 Sep 2020 14:33:46

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:59:01

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:59:01

US3002131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:59:01



**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'VISIT2'	System	04 Sep 2020 15:59:01

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '08:14'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '04 Sep 2020 08:14'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09



US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '83'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'bpm'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'breaths/min'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '140'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'mmHg'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '86'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09



US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'mmHg'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '09:42'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '04 Sep 2020 09:42'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09



US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '86'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'bpm'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'breaths/min'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '136'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'mmHg'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '86'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:09



US3002131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'mmHg'	System	04 Sep 2020 16:00:09

US3002131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:18

US3002131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:18

US3002131

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:31

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:49:23**

*Date of test (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:31

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:49:23**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:31

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:49:23**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:31

US3002131

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 11:02:24
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate. ' answered with 'updated' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	27 Oct 2020 16:41:46
User entered 'No (N)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	27 Oct 2020 16:41:42
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:06:16
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:00:31



US3002131

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:49:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:31

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:49:23**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:31

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered empty.	System	04 Sep 2020 16:00:31

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	04 Sep 2020 14:34:12

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	04 Sep 2020 14:34:12
	(b) (4)	

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

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)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	Tiffany Nemecek (b) (4)	04 Sep 2020 14:34:12

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:49:23**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 14:34:12

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) Tiffany Nemecek (b) (4)	04 Sep 2020 14:34:12
	(b) (4)	



**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:49:23**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '09:09'	(b) (4) Tiffany Nemecek (b) (4)	04 Sep 2020 14:34:12

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '04 Sep 2020 09:09'	System	04 Sep 2020 14:34:12

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Nemecek (b) (4)	04 Sep 2020 14:34:12

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'ONCE'	System	04 Sep 2020 14:34:12

US3002131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 14:34:12

US3002131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:03

US3002131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:03

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '08:43'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:03



**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '04 Sep 2020 08:43'	System	04 Sep 2020 16:01:03

US3002131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:49:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:40

US3002131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 16:01:40

US3002131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:40

US3002131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '08:37'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:40

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '04 Sep 2020 08:37'	System	04 Sep 2020 16:01:40

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 16:01:40

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:40



**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:49:23**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:40

US3002131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered empty.	System	04 Sep 2020 16:01:40

**US3002131**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:47

US3002131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '1'	System	04 Sep 2020 16:01:47

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:43:28', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '487fc3e3-d7d7-447a-9743-90a562de897c' User entered 'Yes (Y)'	System	04 Sep 2020 14:43:43
	System	04 Sep 2020 14:43:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:43:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '487fc3e3-d7d7-447a-9743-90a562de897c' User entered '98.1'	System	04 Sep 2020 14:43:43
	System	04 Sep 2020 14:43:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:43:36', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '487fc3e3-d7d7-447a-9743-90a562de897c' User entered 'No (N)'	System	04 Sep 2020 14:43:43
	System	04 Sep 2020 14:43:43



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:43:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '487fc3e3-d7d7-447a-9743-90a562de897c' User entered '04 Sep 2020 09:43'	System	04 Sep 2020 14:43:43
	System	04 Sep 2020 14:43:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 09:29'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:19:17', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fbad70d4-ce41-4349-b7e9-e26fa905f8e3'	System	05 Sep 2020 00:20:29
User entered 'Yes (Y)'	System	05 Sep 2020 00:20:29

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:20:11', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fbad70d4-ce41-4349-b7e9-e26fa905f8e3'	System	05 Sep 2020 00:20:29
User entered '97.4'	System	05 Sep 2020 00:20:29

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:20:18', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fbad70d4-ce41-4349-b7e9-e26fa905f8e3'	System	05 Sep 2020 00:20:29
User entered 'No (N)'	System	05 Sep 2020 00:20:29

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:20:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fbad70d4-ce41-4349-b7e9-e26fa905f8e3' User entered '04 Sep 2020 18:20'	System	05 Sep 2020 00:20:29
	System	05 Sep 2020 00:20:29



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 12:54'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 2'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:00', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '170eb497-7cfb-4811-a4e6-023b87133285' User entered 'Yes (Y)'	System	06 Sep 2020 00:56:17
	System	06 Sep 2020 00:56:17

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:04', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '170eb497-7cfb-4811-a4e6-023b87133285' User entered '99.9'	System	06 Sep 2020 00:56:17
	System	06 Sep 2020 00:56:17

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:08', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '170eb497-7cfb-4811-a4e6-023b87133285' User entered 'No (N)'	System	06 Sep 2020 00:56:17
	System	06 Sep 2020 00:56:17

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '170eb497-7cfb-4811-a4e6-023b87133285'	System	06 Sep 2020 00:56:17
User entered '05 Sep 2020 18:56'	System	06 Sep 2020 00:56:17

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:34:12



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 3'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:29:24', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'aefb0dfa-63c1-402f-9511-ef0fc3e39675' User entered 'Yes (Y)'	System	07 Sep 2020 00:29:43
	System	07 Sep 2020 00:29:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:29:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'aefb0dfa-63c1-402f-9511-ef0fc3e39675' User entered '97.2'	System	07 Sep 2020 00:29:43
	System	07 Sep 2020 00:29:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:29:36', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'aefb0dfa-63c1-402f-9511-ef0fc3e39675'	System	07 Sep 2020 00:29:43
User entered 'No (N)'	System	07 Sep 2020 00:29:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:29:38', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'aefb0dfa-63c1-402f-9511-ef0fc3e39675'	System	07 Sep 2020 00:29:43
User entered '06 Sep 2020 18:29'	System	07 Sep 2020 00:29:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:34:12



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 4'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:49:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d726b28-0adf-4cb8-acc- ea2a9d4c8046' User entered 'Yes (Y)'	System	07 Sep 2020 23:52:13
	System	07 Sep 2020 23:52:13

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:03', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d726b28-0adf-4cb8-accc-ea2a9d4c8046' User entered '97.8'	System	07 Sep 2020 23:52:13
	System	07 Sep 2020 23:52:13

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d726b28-0adf-4cb8-accc-ea2a9d4c8046'	System	07 Sep 2020 23:52:13
User entered 'No (N)'	System	07 Sep 2020 23:52:13

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:11', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d726b28-0adf-4cb8-accc-ea2a9d4c8046'	System	07 Sep 2020 23:52:13
User entered '07 Sep 2020 18:52'	System	07 Sep 2020 23:52:13

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 5'	System	04 Sep 2020 14:34:12



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:29:28', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d9607e7-9139-4369-a625-de3352bf9d98'	System	08 Sep 2020 23:29:43
User entered 'Yes (Y)'	System	08 Sep 2020 23:29:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:29:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d9607e7-9139-4369-a625-de3352bf9d98' User entered '98.8'	System	08 Sep 2020 23:29:43
	System	08 Sep 2020 23:29:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:29:38', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d9607e7-9139-4369-a625-de3352bf9d98'	System	08 Sep 2020 23:29:43
User entered 'No (N)'	System	08 Sep 2020 23:29:43

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:29:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '5d9607e7-9139-4369-a625-de3352bf9d98'	System	08 Sep 2020 23:29:43
User entered '08 Sep 2020 18:29'	System	08 Sep 2020 23:29:43

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 6'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:49:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '93406e15-98d0-478b-b68a-785039457e5f' User entered 'Yes (Y)'	System	10 Sep 2020 16:49:55
	System	10 Sep 2020 16:49:55



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:49:43', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '93406e15-98d0-478b-b68a-785039457e5f' User entered '97.4'	System	10 Sep 2020 16:49:55
	System	10 Sep 2020 16:49:55

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:49:48', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '93406e15-98d0-478b-b68a-785039457e5f'	System	10 Sep 2020 16:49:55
User entered 'No (N)'	System	10 Sep 2020 16:49:55

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:49:51', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '93406e15-98d0-478b-b68a-785039457e5f' User entered '10 Sep 2020 11:49'	System	10 Sep 2020 16:49:55
	System	10 Sep 2020 16:49:55

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 7'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:20', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '97b3a8db-a732-4122-88f6-24924b59757f' User entered 'Yes (Y)'	System	11 Sep 2020 01:35:38
	System	11 Sep 2020 01:35:38

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '97b3a8db-a732-4122-88f6-24924b59757f' User entered '97.0'	System	11 Sep 2020 01:35:38
	System	11 Sep 2020 01:35:38



US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '97b3a8db-a732-4122-88f6-24924b59757f' User entered 'No (N)'	System	11 Sep 2020 01:35:38
	System	11 Sep 2020 01:35:38

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:35', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '97b3a8db-a732-4122-88f6-24924b59757f' User entered '10 Sep 2020 20:35'	System	11 Sep 2020 01:35:38
	System	11 Sep 2020 01:35:38

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:43:55', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '175ea0b0-c6ea-4973-b9a8-f79fb8dbcb71'	System	04 Sep 2020 14:44:38
User entered 'None (1)'	System	04 Sep 2020 14:44:38

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:43:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '175ea0b0-c6ea-4973-b9a8-f79fb8dbcb71'	System	04 Sep 2020 14:44:38
User entered 'No (N)'	System	04 Sep 2020 14:44:38

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:22', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '175ea0b0-c6ea-4973-b9a8-f79fb8dbcb71' User entered 'No (N)'	System	04 Sep 2020 14:44:38
	System	04 Sep 2020 14:44:38



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:31', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '175ea0b0-c6ea-4973-b9a8-f79fb8dbcb71'	System	04 Sep 2020 14:44:38
User entered 'None (1)'	System	04 Sep 2020 14:44:38

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:34', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '175ea0b0-c6ea-4973-b9a8-f79fb8dbcb71'	System	04 Sep 2020 14:44:38
User entered '04 Sep 2020 09:44'	System	04 Sep 2020 14:44:38

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 09:29'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:20:49', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '55de1519-30c9-4f73-8c5e-03021d5288b8'	System	05 Sep 2020 00:21:55
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 00:21:55

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:21:20', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '55de1519-30c9-4f73-8c5e-03021d5288b8'	System	05 Sep 2020 00:21:55
User entered 'No (N)'	System	05 Sep 2020 00:21:55

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:21:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '55de1519-30c9-4f73-8c5e-03021d5288b8' User entered 'No (N)'	System	05 Sep 2020 00:21:55
	System	05 Sep 2020 00:21:55



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:21:45', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '55de1519-30c9-4f73-8c5e-03021d5288b8'	System	05 Sep 2020 00:21:55
User entered 'None (1)'	System	05 Sep 2020 00:21:55

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:21:50', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '55de1519-30c9-4f73-8c5e-03021d5288b8' User entered '04 Sep 2020 18:21'	System	05 Sep 2020 00:21:55
	System	05 Sep 2020 00:21:55

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 12:54'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 2'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:53:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3af96639-430e-4dee-9ce0-752a700e2ea5'	System	06 Sep 2020 00:56:01
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 00:56:01

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:53:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3af96639-430e-4dee-9ce0-752a700e2ea5' User entered 'Yes (Y)'	System	06 Sep 2020 00:56:01
	System	06 Sep 2020 00:56:01

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:55:28', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3af96639-430e-4dee-9ce0-752a700e2ea5' User entered '12'	System	06 Sep 2020 00:56:01
	System	06 Sep 2020 00:56:01



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:55:49', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3af96639-430e-4dee-9ce0-752a700e2ea5' User entered 'No (N)'	System	06 Sep 2020 00:56:01
	System	06 Sep 2020 00:56:01

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:55:52', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3af96639-430e-4dee-9ce0-752a700e2ea5' User entered 'None (1)'	System	06 Sep 2020 00:56:01
	System	06 Sep 2020 00:56:01

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:55:55', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3af96639-430e-4dee-9ce0-752a700e2ea5' User entered '05 Sep 2020 18:55'	System	06 Sep 2020 00:56:01
	System	06 Sep 2020 00:56:01

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 3'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '750c7389-f51f-4422-997d-2655e97d214d'	System	07 Sep 2020 00:30:42
User entered 'None (1)'	System	07 Sep 2020 00:30:42

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '750c7389-f51f-4422-997d-2655e97d214d' User entered 'No (N)'	System	07 Sep 2020 00:30:42
	System	07 Sep 2020 00:30:42



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:35', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '750c7389-f51f-4422-997d-2655e97d214d' User entered 'No (N)'	System	07 Sep 2020 00:30:42
	System	07 Sep 2020 00:30:42

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:37', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '750c7389-f51f-4422-997d-2655e97d214d' User entered 'None (1)'	System	07 Sep 2020 00:30:42
	System	07 Sep 2020 00:30:42

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:40', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '750c7389-f51f-4422-997d-2655e97d214d' User entered '06 Sep 2020 18:30'	System	07 Sep 2020 00:30:42
	System	07 Sep 2020 00:30:42

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 4'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:15', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e1ce3737-e27f-4492-9cdd-7cb0058d7269'	System	07 Sep 2020 23:52:29
User entered 'None (1)'	System	07 Sep 2020 23:52:29

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:18', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e1ce3737-e27f-4492-9cdd-7cb0058d7269'	System	07 Sep 2020 23:52:29
User entered 'No (N)'	System	07 Sep 2020 23:52:29



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:20', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e1ce3737-e27f-4492-9cdd-7cb0058d7269' User entered 'No (N)'	System	07 Sep 2020 23:52:29
	System	07 Sep 2020 23:52:29

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:24', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e1ce3737-e27f-4492-9cdd-7cb0058d7269'	System	07 Sep 2020 23:52:29
User entered 'None (1)'	System	07 Sep 2020 23:52:29

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e1ce3737-e27f-4492-9cdd-7cb0058d7269' User entered '07 Sep 2020 18:52'	System	07 Sep 2020 23:52:29
	System	07 Sep 2020 23:52:29

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 5'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

**Please record - PAIN AT INJECTION SITE.**

[Please select one response below](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:08', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '996bf638-ebdd-49ca-867a-3c3fb6f14edf' User entered 'None (1)'	System	08 Sep 2020 23:28:19
	System	08 Sep 2020 23:28:19

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:10', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '996bf638-ebdd-49ca-867a-3c3fb6f14edf' User entered 'No (N)'	System	08 Sep 2020 23:28:19
	System	08 Sep 2020 23:28:19



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:13', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '996bf638-ebdd-49ca-867a-3c3fb6f14edf' User entered 'No (N)'	System	08 Sep 2020 23:28:19
	System	08 Sep 2020 23:28:19

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:15', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '996bf638-ebdd-49ca-867a-3c3fb6f14edf' User entered 'None (1)'	System	08 Sep 2020 23:28:19
	System	08 Sep 2020 23:28:19

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:17', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '996bf638-ebdd-49ca-867a-3c3fb6f14edf' User entered '08 Sep 2020 18:28'	System	08 Sep 2020 23:28:19
	System	08 Sep 2020 23:28:19

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 6'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:49:55', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '0d3e926b-2cdf-4a1e-a981-52c8d535617d'	System	10 Sep 2020 16:50:11
User entered 'None (1)'	System	10 Sep 2020 16:50:11

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:49:57', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '0d3e926b-2cdf-4a1e-a981-52c8d535617d' User entered 'No (N)'	System	10 Sep 2020 16:50:11
	System	10 Sep 2020 16:50:11



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:49:59', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '0d3e926b-2cdf-4a1e-a981-52c8d535617d' User entered 'No (N)'	System	10 Sep 2020 16:50:11
	System	10 Sep 2020 16:50:11

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '0d3e926b-2cdf-4a1e-a981-52c8d535617d' User entered 'None (1)'	System	10 Sep 2020 16:50:11
	System	10 Sep 2020 16:50:11

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:04', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '0d3e926b-2cdf-4a1e-a981-52c8d535617d' User entered '10 Sep 2020 11:50'	System	10 Sep 2020 16:50:11
	System	10 Sep 2020 16:50:11

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 7'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a3e1d20c-9897-4032-a3ee-812a60058676' User entered 'None (1)'	System	11 Sep 2020 01:36:05
	System	11 Sep 2020 01:36:05

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a3e1d20c-9897-4032-a3ee-812a60058676' User entered 'No (N)'	System	11 Sep 2020 01:36:05
	System	11 Sep 2020 01:36:05



US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:43', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a3e1d20c-9897-4032-a3ee-812a60058676' User entered 'No (N)'	System	11 Sep 2020 01:36:05
	System	11 Sep 2020 01:36:05

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:35:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a3e1d20c-9897-4032-a3ee-812a60058676' User entered 'None (1)'	System	11 Sep 2020 01:36:05
	System	11 Sep 2020 01:36:05

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:01', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'a3e1d20c-9897-4032-a3ee-812a60058676' User entered '10 Sep 2020 20:36'	System	11 Sep 2020 01:36:05
	System	11 Sep 2020 01:36:05

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48' User entered 'None (0)'	System	04 Sep 2020 14:45:13
	System	04 Sep 2020 14:45:13

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:48', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48' User entered 'None (0)'	System	04 Sep 2020 14:45:13
	System	04 Sep 2020 14:45:13



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:51', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48' User entered 'None (0)'	System	04 Sep 2020 14:45:13
	System	04 Sep 2020 14:45:13

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:52', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48' User entered 'None (0)'	System	04 Sep 2020 14:45:13
	System	04 Sep 2020 14:45:13

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:54', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48' User entered 'None (0)'	System	04 Sep 2020 14:45:13
	System	04 Sep 2020 14:45:13

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:44:56', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48' User entered 'None (0)'	System	04 Sep 2020 14:45:13
	System	04 Sep 2020 14:45:13

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:45:01', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48'	System	04 Sep 2020 14:45:13
User entered 'No (N)'	System	04 Sep 2020 14:45:13

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T09:45:11', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '554d9f36-c862-4f7b-ae89-5fc8b0bd7b48'	System	04 Sep 2020 14:45:13
User entered '04 Sep 2020 09:45'	System	04 Sep 2020 14:45:13

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 09:29'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 14:34:12



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Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:09', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered 'No interference with activity (1)'	System	05 Sep 2020 00:22:28

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:12', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered 'None (0)'	System	05 Sep 2020 00:22:28

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered 'None (0)'	System	05 Sep 2020 00:22:28

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:16', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered 'None (0)'	System	05 Sep 2020 00:22:28

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:18', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered 'None (0)'	System	05 Sep 2020 00:22:28

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:20', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered 'None (0)'	System	05 Sep 2020 00:22:28

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:23', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered 'No (N)'	System	05 Sep 2020 00:22:28



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Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-04T18:22:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e744c315-93e8-4751-88dc-75ea3fc7d522'	System	05 Sep 2020 00:22:28
User entered '04 Sep 2020 18:22'	System	05 Sep 2020 00:22:28

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '04 Sep 2020 12:54'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 2'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:21', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered 'None (0)'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:24', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered 'None (0)'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered 'None (0)'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:44', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered 'None (0)'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:46', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered 'None (0)'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:50', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered 'None (0)'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:54', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered 'No (N)'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-05T18:56:57', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '03c1edc6-a4ce-4389-9841-37c02e29910a' User entered '05 Sep 2020 18:56'	System	06 Sep 2020 00:56:59
	System	06 Sep 2020 00:56:59

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 3'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:47', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5' User entered 'None (0)'	System	07 Sep 2020 00:31:08
	System	07 Sep 2020 00:31:08



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:51', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5'	System	07 Sep 2020 00:31:08
User entered 'None (0)'	System	07 Sep 2020 00:31:08

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:53', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5'	System	07 Sep 2020 00:31:08
User entered 'None (0)'	System	07 Sep 2020 00:31:08

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:54', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5' User entered 'None (0)'	System	07 Sep 2020 00:31:08
	System	07 Sep 2020 00:31:08

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:56', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5' User entered 'None (0)'	System	07 Sep 2020 00:31:08
	System	07 Sep 2020 00:31:08

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:30:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5'	System	07 Sep 2020 00:31:08
User entered 'None (0)'	System	07 Sep 2020 00:31:08

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:31:03', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5'	System	07 Sep 2020 00:31:08
User entered 'No (N)'	System	07 Sep 2020 00:31:08

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-06T18:31:05', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd296aca4-bdc6-44d7-b684-40ab73efffd5' User entered '06 Sep 2020 18:31'	System	07 Sep 2020 00:31:08
	System	07 Sep 2020 00:31:08

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:34:12



**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 4'	System	04 Sep 2020 14:34:12

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133'	System	07 Sep 2020 23:52:46
User entered 'None (0)'	System	07 Sep 2020 23:52:46

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133' User entered 'None (0)'	System	07 Sep 2020 23:52:46
	System	07 Sep 2020 23:52:46

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:34', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133' User entered 'None (0)'	System	07 Sep 2020 23:52:46
	System	07 Sep 2020 23:52:46

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:35', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133' User entered 'None (0)'	System	07 Sep 2020 23:52:46
	System	07 Sep 2020 23:52:46

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:37', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133' User entered 'None (0)'	System	07 Sep 2020 23:52:46
	System	07 Sep 2020 23:52:46

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:38', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133' User entered 'None (0)'	System	07 Sep 2020 23:52:46
	System	07 Sep 2020 23:52:46



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133'	System	07 Sep 2020 23:52:46
User entered 'No (N)'	System	07 Sep 2020 23:52:46

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-07T18:52:44', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '974649a9-0058-4c72-8b71-0aec77c02133'	System	07 Sep 2020 23:52:46
User entered '07 Sep 2020 18:52'	System	07 Sep 2020 23:52:46

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 5'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:21', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef' User entered 'None (0)'	System	08 Sep 2020 23:28:42
	System	08 Sep 2020 23:28:42

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:24', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef' User entered 'None (0)'	System	08 Sep 2020 23:28:42
	System	08 Sep 2020 23:28:42

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:28', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef' User entered 'None (0)'	System	08 Sep 2020 23:28:42
	System	08 Sep 2020 23:28:42



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef' User entered 'None (0)'	System	08 Sep 2020 23:28:42
	System	08 Sep 2020 23:28:42

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef' User entered 'None (0)'	System	08 Sep 2020 23:28:42
	System	08 Sep 2020 23:28:42

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:35', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef' User entered 'None (0)'	System	08 Sep 2020 23:28:42
	System	08 Sep 2020 23:28:42

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:37', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef'	System	08 Sep 2020 23:28:42
User entered 'No (N)'	System	08 Sep 2020 23:28:42

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-08T18:28:40', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '089f01cb-9074-44fb-9349-613d4eeb2bef'	System	08 Sep 2020 23:28:42
User entered '08 Sep 2020 18:28'	System	08 Sep 2020 23:28:42

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 6'	System	04 Sep 2020 14:34:12



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:07', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered 'None (0)'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:08', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered 'None (0)'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:10', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered 'None (0)'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:11', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered 'None (0)'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:13', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered 'None (0)'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered 'None (0)'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:17', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered 'No (N)'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T11:50:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e6942603-10e2-4187-b785-ec2d23204b7a' User entered '10 Sep 2020 11:50'	System	10 Sep 2020 16:50:23
	System	10 Sep 2020 16:50:23



**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	04 Sep 2020 14:34:12
User entered 'Day 7'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:18', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered 'None (0)'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:20', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered 'None (0)'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:21', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered 'None (0)'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:24', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered 'None (0)'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:25', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered 'None (0)'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37



US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered 'None (0)'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37

US3002131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:23

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)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered 'No (N)'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-09-10T20:36:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6412b23d-a532-48da-bea7-81ddf411fbc1' User entered '10 Sep 2020 20:36'	System	11 Sep 2020 01:36:37
	System	11 Sep 2020 01:36:37

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:34:12

**US3002131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:49:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:34:12

US3002131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	Brandon Essink (b) (4)	11 Sep 2020 13:34:19

US3002131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '11 Sep 2020'	Brandon Essink (b) (4)	11 Sep 2020 13:34:19

US3002131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	Brandon Essink (b) (4)	11 Sep 2020 13:34:19



US3002131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	Brandon Essink (b) (4)	11 Sep 2020 13:34:19

US3002131

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) Brandon Essink (b) (4)	11 Sep 2020 13:34:27

**US3002131**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered '1'	System	11 Sep 2020 13:34:27

**US3002131**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:10

**US3002131**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:10

US3002131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:10

US3002131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:10

US3002131

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:13



US3002131

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered '1'	System	28 Sep 2020 19:58:13

**US3002131**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:26

**US3002131**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:26

US3002131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:26

US3002131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:26

US3002131

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:58:30

**US3002131**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered '1'	System	28 Sep 2020 19:58:30

US3002131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:43:46



US3002131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:43:46

US3002131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:43:46

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered 'VISIT3'	System	02 Oct 2020 15:43:46

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '08:07'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered '02 Oct 2020 08:07'	System	02 Oct 2020 15:44:06

US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '37.2' C	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06



**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '90'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered 'bpm'	System	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '15'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered 'breaths/min'	System	02 Oct 2020 15:44:06

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '130'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered 'mmHg'	System	02 Oct 2020 15:44:06



US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '80'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:44:06

US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered 'mmHg'	System	02 Oct 2020 15:44:06

US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03

US3002131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03

US3002131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:45:36

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:49:23**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:45:36

US3002131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:47:17

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

*Collection date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:47:17



US3002131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '08:27'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:47:17

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered '02 Oct 2020 08:27'	System	02 Oct 2020 15:47:17

US3002131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:10:30
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). User signature succeeded.	Kimberly Mueller (b) (4)	27 Mar 2021 20:51:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	09 Mar 2021 10:50:05
User entered 'Yes (Y)'	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
	(b) (4), (b) (6)	02 Oct 2020 15:47:20

**US3002131**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered '1'	System	02 Oct 2020 15:47:20

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 64'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-10T20:09:53', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '379d8d34-44fd-45a0-b5d7-eccab1dd0757'	System	11 Oct 2020 01:12:17
User entered 'No (N)'	System	11 Oct 2020 01:12:17

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-10T20:11:48', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '379d8d34-44fd-45a0-b5d7-eccab1dd0757'	System	11 Oct 2020 01:12:17
User entered 'Yes (Y)'	System	11 Oct 2020 01:12:17

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please 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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-10T20:11:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '379d8d34-44fd-45a0-b5d7-eccab1dd0757'	System	11 Oct 2020 01:12:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Oct 2020 01:12:17



**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-10T20:12:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '379d8d34-44fd-45a0-b5d7-eccab1dd0757' User entered '10 Oct 2020 20:12:06'	System	11 Oct 2020 01:12:17
	System	11 Oct 2020 01:12:17

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 71'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-16T12:26:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '82edf01b-9afc-4891-ad55-ccd17aa69d64'	System	16 Oct 2020 17:26:59
User entered 'No (N)'	System	16 Oct 2020 17:26:59

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-16T12:26:48', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '82edf01b-9afc-4891-ad55-ccd17aa69d64'	System	16 Oct 2020 17:26:59
User entered 'No (N)'	System	16 Oct 2020 17:26:59

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-16T12:26:53', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '82edf01b-9afc-4891-ad55-ccd17aa69d64' User entered '16 Oct 2020 12:26:53'	System	16 Oct 2020 17:26:59
	System	16 Oct 2020 17:26:59

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 18:26:25



US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 78'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-21T00:01:54', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9f89780c-b008-4411-a0f4-8a4525ac6e1f'	System	21 Oct 2020 05:02:08
User entered 'No (N)'	System	21 Oct 2020 05:02:08

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-21T00:01:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9f89780c-b008-4411-a0f4-8a4525ac6e1f'	System	21 Oct 2020 05:02:08
User entered 'No (N)'	System	21 Oct 2020 05:02:08

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-10-21T00:02:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9f89780c-b008-4411-a0f4-8a4525ac6e1f' User entered '21 Oct 2020 00:02:02'	System	21 Oct 2020 05:02:08
	System	21 Oct 2020 05:02:08

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 92'	System	07 Aug 2020 18:26:25



**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-04T01:04:23', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ea9a1917-928b-4084-b0e5-5a67b7437091'	System	04 Nov 2020 07:04:35
User entered 'No (N)'	System	04 Nov 2020 07:04:35

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-04T01:04:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ea9a1917-928b-4084-b0e5-5a67b7437091'	System	04 Nov 2020 07:04:35
User entered 'No (N)'	System	04 Nov 2020 07:04:35

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-04T01:04:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'ea9a1917-928b-4084-b0e5-5a67b7437091' User entered '04 Nov 2020 01:04:32'	System	04 Nov 2020 07:04:35
	System	04 Nov 2020 07:04:35

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 99'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-11T21:03:49', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '610f3ed4-5c24-4116-8b55-3ed40804e762'	System	12 Nov 2020 03:04:01
User entered 'No (N)'	System	12 Nov 2020 03:04:01

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-11T21:03:54', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '610f3ed4-5c24-4116-8b55-3ed40804e762'	System	12 Nov 2020 03:04:01
User entered 'No (N)'	System	12 Nov 2020 03:04:01



**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-11T21:03:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '610f3ed4-5c24-4116-8b55-3ed40804e762' User entered '11 Nov 2020 21:03:58'	System	12 Nov 2020 03:04:01
	System	12 Nov 2020 03:04:01

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:55
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09
Data entry locked.	System	07 Aug 2020 18:26:25
User entered 'Day 106'	System	07 Aug 2020 18:26:25

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please 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 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

US3002131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please 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 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please 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 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:09
Data entry locked.	System	07 Aug 2020 18:26:25
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 18:26:25

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:59:09



US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-19T19:56:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '77c639e6-5d7c-4d51-be24-b9d246720b5a' User entered 'No (N)'	System	20 Nov 2020 01:56:57
	System	20 Nov 2020 01:56:57

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-19T19:56:52', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '77c639e6-5d7c-4d51-be24-b9d246720b5a' User entered 'No (N)'	System	20 Nov 2020 01:56:57
	System	20 Nov 2020 01:56:57

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-19T19:56:55', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '77c639e6-5d7c-4d51-be24-b9d246720b5a' User entered '19 Nov 2020 19:56:55'	System	20 Nov 2020 01:56:57
	System	20 Nov 2020 01:56:57

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-23T17:50:00', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c392253b-0474-4b51-a610-21fe4bb10634'	System	23 Nov 2020 23:50:10
User entered 'No (N)'	System	23 Nov 2020 23:50:10

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-23T17:50:02', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c392253b-0474-4b51-a610-21fe4bb10634'	System	23 Nov 2020 23:50:10
User entered 'No (N)'	System	23 Nov 2020 23:50:10



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-23T17:50:05', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c392253b-0474-4b51-a610-21fe4bb10634'	System	23 Nov 2020 23:50:10
User entered '23 Nov 2020 17:50:05'	System	23 Nov 2020 23:50:10

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-29T17:13:57', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c527b568-5c75-46c2-9aeb-d03c790eb16f' User entered 'No (N)'	System	29 Nov 2020 23:14:08
	System	29 Nov 2020 23:14:08

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-29T17:13:59', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c527b568-5c75-46c2-9aeb-d03c790eb16f'	System	29 Nov 2020 23:14:08
User entered 'No (N)'	System	29 Nov 2020 23:14:08

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-11-29T17:14:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c527b568-5c75-46c2-9aeb-d03c790eb16f' User entered '29 Nov 2020 17:14:06'	System	29 Nov 2020 23:14:08
	System	29 Nov 2020 23:14:08

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-07T09:15:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9c0db1a-6faa-454b-941f-dae642d953ab'	System	07 Dec 2020 15:16:38
User entered 'Yes (Y)'	System	07 Dec 2020 15:16:38

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-07T09:15:25', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9c0db1a-6faa-454b-941f-dae642d953ab'	System	07 Dec 2020 15:16:38
User entered 'No (N)'	System	07 Dec 2020 15:16:38

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-07T09:15:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9c0db1a-6faa-454b-941f-dae642d953ab'	System	07 Dec 2020 15:16:38
User entered 'No (N)'	System	07 Dec 2020 15:16:38

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-07T09:15:34', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9c0db1a-6faa-454b-941f-dae642d953ab'	System	07 Dec 2020 15:16:38
User entered 'Yes (Y)'	System	07 Dec 2020 15:16:38

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-07T09:15:43', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9c0db1a-6faa-454b-941f-dae642d953ab'	System	07 Dec 2020 15:16:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 15:16:38

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-07T09:16:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9c0db1a-6faa-454b-941f-dae642d953ab'	System	07 Dec 2020 15:16:38
User entered '07 Dec 2020 09:16:27'	System	07 Dec 2020 15:16:38



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:30:07
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'See SAE of venous thromboembolism for details reported at this call' (Site from DM).	Kimberly Mueller (b) (4)	27 Mar 2021 20:50:46
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 07:01:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-14T21:29:40', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9663663a-1621-40ce-a1c0-84174bbe3b30'	System	15 Dec 2020 03:30:10
User entered 'Yes (Y)'	System	15 Dec 2020 03:30:10

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-14T21:29:43', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9663663a-1621-40ce-a1c0-84174bbe3b30'	System	15 Dec 2020 03:30:10
User entered 'No (N)'	System	15 Dec 2020 03:30:10

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-14T21:29:47', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9663663a-1621-40ce-a1c0-84174bbe3b30'	System	15 Dec 2020 03:30:10
User entered 'No (N)'	System	15 Dec 2020 03:30:10

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-14T21:29:52', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9663663a-1621-40ce-a1c0-84174bbe3b30'	System	15 Dec 2020 03:30:10
User entered 'Yes (Y)'	System	15 Dec 2020 03:30:10

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-14T21:29:56', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9663663a-1621-40ce-a1c0-84174bbe3b30'	System	15 Dec 2020 03:30:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Dec 2020 03:30:10



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-14T21:29:58', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '9663663a-1621-40ce-a1c0-84174bbe3b30'	System	15 Dec 2020 03:30:10
User entered '14 Dec 2020 21:29:58'	System	15 Dec 2020 03:30:10

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-20T06:17:18', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e5fe9047-cb68-482e-a87a-00a04a0b892c'	System	20 Dec 2020 12:17:28
User entered 'No (N)'	System	20 Dec 2020 12:17:28

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-20T06:17:21', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e5fe9047-cb68-482e-a87a-00a04a0b892c'	System	20 Dec 2020 12:17:28
User entered 'No (N)'	System	20 Dec 2020 12:17:28

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-20T06:17:26', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e5fe9047-cb68-482e-a87a-00a04a0b892c' User entered '20 Dec 2020 06:17:26'	System	20 Dec 2020 12:17:28
	System	20 Dec 2020 12:17:28

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-27T18:12:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '63dda14f-4161-4c20-9383-067c69d2d6d4'	System	28 Dec 2020 00:12:43
User entered 'No (N)'	System	28 Dec 2020 00:12:43

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-27T18:12:36', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '63dda14f-4161-4c20-9383-067c69d2d6d4'	System	28 Dec 2020 00:12:43
User entered 'No (N)'	System	28 Dec 2020 00:12:43

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2020-12-27T18:12:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '63dda14f-4161-4c20-9383-067c69d2d6d4'	System	28 Dec 2020 00:12:43
User entered '27 Dec 2020 18:12:39'	System	28 Dec 2020 00:12:43

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:59:09



US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-03T12:06:01', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '572b0fe7-abe2-4bbd-9730-156ffe98c7fb'	System	03 Jan 2021 18:06:30
User entered 'Yes (Y)'	System	03 Jan 2021 18:06:30

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-03T12:06:04', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '572b0fe7-abe2-4bbd-9730-156ffe98c7fb' User entered 'No (N)'	System	03 Jan 2021 18:06:30
	System	03 Jan 2021 18:06:30

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-03T12:06:07', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '572b0fe7-abe2-4bbd-9730-156ffe98c7fb' User entered 'No (N)'	System	03 Jan 2021 18:06:30
	System	03 Jan 2021 18:06:30

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-03T12:06:12', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '572b0fe7-abe2-4bbd-9730-156ffe98c7fb'	System	03 Jan 2021 18:06:30
User entered 'Yes (Y)'	System	03 Jan 2021 18:06:30

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-03T12:06:16', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '572b0fe7-abe2-4bbd-9730-156ffe98c7fb'	System	03 Jan 2021 18:06:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 18:06:30

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-03T12:06:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '572b0fe7-abe2-4bbd-9730-156ffe98c7fb' User entered '03 Jan 2021 12:06:19'	System	03 Jan 2021 18:06:30
	System	03 Jan 2021 18:06:30

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-10T10:38:34', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd20f5ba2-bb8a-4487-9194-88c30ca28b33'	System	10 Jan 2021 16:38:59
User entered 'Yes (Y)'	System	10 Jan 2021 16:38:59

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-10T10:38:37', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd20f5ba2-bb8a-4487-9194-88c30ca28b33'	System	10 Jan 2021 16:38:59
User entered 'No (N)'	System	10 Jan 2021 16:38:59

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-10T10:38:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd20f5ba2-bb8a-4487-9194-88c30ca28b33'	System	10 Jan 2021 16:38:59
User entered 'No (N)'	System	10 Jan 2021 16:38:59

US3002131

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:49:23

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-10T10:38:43', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd20f5ba2-bb8a-4487-9194-88c30ca28b33'	System	10 Jan 2021 16:38:59
User entered 'Yes (Y)'	System	10 Jan 2021 16:38:59

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-10T10:38:47', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd20f5ba2-bb8a-4487-9194-88c30ca28b33'	System	10 Jan 2021 16:38:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 16:38:59

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-10T10:38:49', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd20f5ba2-bb8a-4487-9194-88c30ca28b33' User entered '10 Jan 2021 10:38:49'	System	10 Jan 2021 16:38:59
	System	10 Jan 2021 16:38:59

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-19T12:00:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '36656764-eb5c-4b28-b956-70c2706e1ff1' User entered 'No (N)'	System	19 Jan 2021 18:00:54
	System	19 Jan 2021 18:00:54

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-19T12:00:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '36656764-eb5c-4b28-b956-70c2706e1ff1' User entered 'No (N)'	System	19 Jan 2021 18:00:54
	System	19 Jan 2021 18:00:54

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-19T12:00:37', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '36656764-eb5c-4b28-b956-70c2706e1ff1' User entered '19 Jan 2021 12:00:37'	System	19 Jan 2021 18:00:54
	System	19 Jan 2021 18:00:54

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:59:09



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-24T02:09:12', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '22d9adf0-26b6-4fd6-8a4d-76e2237d3297'	System	24 Jan 2021 08:09:21
User entered 'No (N)'	System	24 Jan 2021 08:09:21

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-24T02:09:15', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '22d9adf0-26b6-4fd6-8a4d-76e2237d3297'	System	24 Jan 2021 08:09:21
User entered 'No (N)'	System	24 Jan 2021 08:09:21

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-24T02:09:19', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '22d9adf0-26b6-4fd6-8a4d-76e2237d3297' User entered '24 Jan 2021 02:09:19'	System	24 Jan 2021 08:09:21
	System	24 Jan 2021 08:09:21

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:59:09

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:59:09

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-31T00:09:26', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '80ff5e37-4502-466a-bc61-f72f49f6e011'	System	31 Jan 2021 06:09:39
User entered 'No (N)'	System	31 Jan 2021 06:09:39

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-31T00:09:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '80ff5e37-4502-466a-bc61-f72f49f6e011'	System	31 Jan 2021 06:09:39
User entered 'No (N)'	System	31 Jan 2021 06:09:39



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-01-31T00:09:33', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '80ff5e37-4502-466a-bc61-f72f49f6e011' User entered '31 Jan 2021 00:09:33'	System	31 Jan 2021 06:09:39
	System	31 Jan 2021 06:09:39

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:59:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:59:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:59:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-08T03:06:24', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '36c27867-93c9-404d-a14e-92c3cdc04370'	System	08 Feb 2021 09:06:33
User entered 'No (N)'	System	08 Feb 2021 09:06:33

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-08T03:06:27', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '36c27867-93c9-404d-a14e-92c3cdc04370'	System	08 Feb 2021 09:06:33
User entered 'No (N)'	System	08 Feb 2021 09:06:33

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-08T03:06:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '36c27867-93c9-404d-a14e-92c3cdc04370'	System	08 Feb 2021 09:06:33
User entered '08 Feb 2021 03:06:29'	System	08 Feb 2021 09:06:33

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:59:09



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:59:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-15T14:24:38', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '52730794-ff99-4370-b771-d565761618c5'	System	15 Feb 2021 20:24:45
User entered 'No (N)'	System	15 Feb 2021 20:24:45

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-15T14:24:41', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '52730794-ff99-4370-b771-d565761618c5'	System	15 Feb 2021 20:24:45
User entered 'No (N)'	System	15 Feb 2021 20:24:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-15T14:24:43', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '52730794-ff99-4370-b771-d565761618c5'	System	15 Feb 2021 20:24:45
User entered '15 Feb 2021 14:24:43'	System	15 Feb 2021 20:24:45

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:59:09



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-21T04:22:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c6af3b3a-7d19-4c58-935d-3454bcd19ad9'	System	23 Feb 2021 23:51:57
User entered 'No (N)'	System	23 Feb 2021 23:51:57

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-21T04:22:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c6af3b3a-7d19-4c58-935d-3454bcd19ad9' User entered 'No (N)'	System	23 Feb 2021 23:51:57
	System	23 Feb 2021 23:51:57

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-21T04:22:47', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'c6af3b3a-7d19-4c58-935d-3454bcd19ad9'	System	23 Feb 2021 23:51:57
User entered '21 Feb 2021 04:22:47'	System	23 Feb 2021 23:51:57

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-28T09:05:50', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fd6a8967-4ae4-479b-b220-9a8ee8c5f96c'	System	28 Feb 2021 15:05:58
User entered 'No (N)'	System	28 Feb 2021 15:05:58

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-28T09:05:52', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fd6a8967-4ae4-479b-b220-9a8ee8c5f96c'	System	28 Feb 2021 15:05:58
User entered 'No (N)'	System	28 Feb 2021 15:05:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-28T09:05:56', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fd6a8967-4ae4-479b-b220-9a8ee8c5f96c'	System	28 Feb 2021 15:05:58
User entered '28 Feb 2021 09:05:56'	System	28 Feb 2021 15:05:58

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-08T17:23:39', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7e03f821-e926-4370-83c8-fd7ec9fbf82d'	System	08 Mar 2021 23:25:26
User entered 'No (N)'	System	08 Mar 2021 23:25:26

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-08T17:23:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7e03f821-e926-4370-83c8-fd7ec9fbf82d'	System	08 Mar 2021 23:25:26
User entered 'No (N)'	System	08 Mar 2021 23:25:26

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-08T17:23:44', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7e03f821-e926-4370-83c8-fd7ec9fbf82d' User entered '08 Mar 2021 17:23:44'	System	08 Mar 2021 23:25:26
	System	08 Mar 2021 23:25:26

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-14T00:01:30', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9d3f7ab-2214-41ad-bce5-d7d95331f3ab'	System	14 Mar 2021 06:01:40
User entered 'No (N)'	System	14 Mar 2021 06:01:40

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-14T00:01:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9d3f7ab-2214-41ad-bce5-d7d95331f3ab'	System	14 Mar 2021 06:01:40
User entered 'No (N)'	System	14 Mar 2021 06:01:40

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-14T00:01:35', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'd9d3f7ab-2214-41ad-bce5-d7d95331f3ab' User entered '14 Mar 2021 00:01:35'	System	14 Mar 2021 06:01:40
	System	14 Mar 2021 06:01:40

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-22T06:45:51', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6c43fc92-73fa-4e9f-b9ba-29c7cbdc0da4'	System	22 Mar 2021 11:46:02
User entered 'No (N)'	System	22 Mar 2021 11:46:02

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-22T06:45:54', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6c43fc92-73fa-4e9f-b9ba-29c7cbdc0da4'	System	22 Mar 2021 11:46:02
User entered 'No (N)'	System	22 Mar 2021 11:46:02

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-22T06:45:57', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '6c43fc92-73fa-4e9f-b9ba-29c7cbdc0da4' User entered '22 Mar 2021 06:45:57'	System	22 Mar 2021 11:46:02
	System	22 Mar 2021 11:46:02

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-29T12:18:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '87123178-6626-4dc0-afba-770096367eb2' User entered 'No (N)'	System	29 Mar 2021 17:18:16
	System	29 Mar 2021 17:18:16

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-29T12:18:08', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '87123178-6626-4dc0-afba-770096367eb2' User entered 'No (N)'	System	29 Mar 2021 17:18:16
	System	29 Mar 2021 17:18:16



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-03-29T12:18:11', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '87123178-6626-4dc0-afba-770096367eb2' User entered '29 Mar 2021 12:18:11'	System	29 Mar 2021 17:18:16
	System	29 Mar 2021 17:18:16

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-04T00:03:26', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fd04e00c-4655-4aef-ac4f-6a1ac91274ad'	System	04 Apr 2021 05:03:53
User entered 'No (N)'	System	04 Apr 2021 05:03:53

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-04T00:03:29', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fd04e00c-4655-4aef-ac4f-6a1ac91274ad'	System	04 Apr 2021 05:03:53
User entered 'No (N)'	System	04 Apr 2021 05:03:53

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-04T00:03:32', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'fd04e00c-4655-4aef-ac4f-6a1ac91274ad' User entered '04 Apr 2021 00:03:32'	System	04 Apr 2021 05:03:53
	System	04 Apr 2021 05:03:53

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-14T18:12:08', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3511eea1-ea6c-4b16-80cd-4992de923ada'	System	14 Apr 2021 23:12:15
User entered 'No (N)'	System	14 Apr 2021 23:12:15

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-14T18:12:10', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3511eea1-ea6c-4b16-80cd-4992de923ada'	System	14 Apr 2021 23:12:15
User entered 'No (N)'	System	14 Apr 2021 23:12:15

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-14T18:12:13', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '3511eea1-ea6c-4b16-80cd-4992de923ada' User entered '14 Apr 2021 18:12:13'	System	14 Apr 2021 23:12:15
	System	14 Apr 2021 23:12:15

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:59:09



US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-18T14:01:40', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7950380a-d128-466e-9cdf-6ce7fe9503f3'	System	18 Apr 2021 19:02:23
User entered 'No (N)'	System	18 Apr 2021 19:02:23

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-18T14:01:42', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7950380a-d128-466e-9cdf-6ce7fe9503f3'	System	18 Apr 2021 19:02:23
User entered 'No (N)'	System	18 Apr 2021 19:02:23

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-18T14:01:44', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '7950380a-d128-466e-9cdf-6ce7fe9503f3'	System	18 Apr 2021 19:02:23
User entered '18 Apr 2021 14:01:44'	System	18 Apr 2021 19:02:23

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:59:09

US3002131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:23

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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-28T18:42:10', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1997f964-353a-4932-9a7c-5957a128006d'	System	28 Apr 2021 23:42:17
User entered 'No (N)'	System	28 Apr 2021 23:42:17

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-28T18:42:12', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1997f964-353a-4932-9a7c-5957a128006d'	System	28 Apr 2021 23:42:17
User entered 'No (N)'	System	28 Apr 2021 23:42:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-04-28T18:42:14', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: '1997f964-353a-4932-9a7c-5957a128006d' User entered '28 Apr 2021 18:42:14'	System	28 Apr 2021 23:42:17
	System	28 Apr 2021 23:42:17

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-05-02T01:16:40', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e5220af5-893d-4c69-8b4c-810241be0fb2'	System	02 May 2021 06:16:51
User entered 'No (N)'	System	02 May 2021 06:16:51

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Have you been exposed to someone with 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 (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-05-02T01:16:44', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e5220af5-893d-4c69-8b4c-810241be0fb2'	System	02 May 2021 06:16:51
User entered 'No (N)'	System	02 May 2021 06:16:51

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-05-02T01:16:47', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e5220af5-893d-4c69-8b4c-810241be0fb2'	System	02 May 2021 06:16:51
User entered '02 May 2021 01:16:47'	System	02 May 2021 06:16:51

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:59:09



**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:59:09

**US3002131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:09
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:59:09

US3002131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:49:23

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 06:37:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-28T09:06:06', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e1903bc9-f081-493e-b84a-9ddbcecc395ad'	System	28 Feb 2021 15:06:13
User entered 'No (N)'	System	28 Feb 2021 15:06:13

US3002131

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:49:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A07A7794-C219-46EA-B67E-6815D68A8E34)', Time: '2021-02-28T09:06:09', User OID: 'PatientReportedOutcome (US3002131)', ODM File OID: 'e1903bc9-f081-493e-b84a-9ddbcecc395ad' User entered '28 Feb 2021 09:06:09'	System	28 Feb 2021 15:06:13
	System	28 Feb 2021 15:06:13

US3002131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:06:00

**US3002131**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:06:00

US3002131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:06:00

US3002131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 14:06:00



US3002131

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:02:00

US3002131

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:32:03
User entered '1'	System	03 Dec 2020 18:02:00

**US3002131**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:02:12

**US3002131**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:02:12

US3002131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:02:12

**US3002131**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:02:12

US3002131

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:02:17

**US3002131**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered '1'	System	03 Dec 2020 18:02:17



US3002131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:35:24
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	16 Jan 2021 04:26:25

US3002131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:35:24
User entered '05 Jan 2021'	Jessica Satorie (b) (4) (b) (4)	16 Jan 2021 04:26:25

US3002131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:35:24
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4) (b) (4)	16 Jan 2021 04:26:25

**US3002131**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:35:24
User entered empty.	Jessica Satorie (b) (4) (b) (4)	16 Jan 2021 04:26:25

US3002131

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 16:35:13
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Jan 2021 04:25:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Jan 2021 04:25:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Satorie (b) (4) (b) (4)	16 Jan 2021 04:25:55
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Jan 2021 04:15:19
User entered empty.	Jessica Satorie (b) (4) (b) (4)	16 Jan 2021 04:15:19

**US3002131**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered '1'	System	16 Jan 2021 04:25:55
User entered empty.	System	16 Jan 2021 04:15:19

**US3002131**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:41:03

**US3002131**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:15:39
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:41:03



US3002131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:15:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:41:03

**US3002131**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:49:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:15:39
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:41:03

US3002131

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	05 Mar 2021 18:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:41:22

**US3002131**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered 'I'	System	03 Mar 2021 14:41:22

US3002131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:04

US3002131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:04

US3002131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:04

**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered 'VISIT4'	System	11 Mar 2021 22:33:04



US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17

**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered empty.	System	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17
	(b) (4)	

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17

**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17



**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:23**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered empty.	System	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered empty.	System	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17
	(b) (4)	

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered empty.	System	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered empty.	System	27 Mar 2021 20:52:17

US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28



US3002131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:23

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28

US3002131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:21

US3002131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:21

US3002131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:29

**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

*Collection date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:29

US3002131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered '08:54'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:29

**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered '19 Feb 2021 08:54'	System	11 Mar 2021 22:33:29

**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:33:31



**US3002131**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:48:28
User entered '1'	System	11 Mar 2021 22:33:31

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:16:53
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:53:48

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:16:53
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:53:48

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:16:53
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:53:48

**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:49:23**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 18:53:48

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:49:23

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:00
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:02

**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:49:23**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:54:05

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:49:23

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:00
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:02



**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:49:23**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:54:05

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:49:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:00
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:02

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:49:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:00
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:02

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:49:23

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:00
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
System		20 Jan 2021 06:41:24
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	12 Jan 2021 18:54:02

**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:49:23**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:00
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 06:41:24
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	12 Jan 2021 18:54:02

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:49:23

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:00
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:02

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:49:23

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered empty.	System	12 Jan 2021 18:54:02

**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:49:23**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered empty.	System	12 Jan 2021 18:54:02



US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:17

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:17

**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '08:13'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:17

**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '12 Jan 2021 08:13'	System	12 Jan 2021 18:54:17

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:25
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:26

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:25
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:26

US3002131

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:25
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '08:29'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 18:54:26

**US3002131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:49:23**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:29:11
User entered '12 Jan 2021 08:29'	System	12 Jan 2021 18:54:26



US3002131

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:49:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:19:07
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:18
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	09 Dec 2020 23:08:57
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:02:08

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:17:05
User entered 'USA-US005-2020-mRNA-1273-P301000012'	System	10 Dec 2020 17:15:32
User entered 'New'	(b) (4), (b) (6)	10 Dec 2020 17:15:32

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Embolism venous, LLT: Venous thromboembolism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 23:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 23:21:42
Data point term sent to Coder	System	09 Dec 2020 23:20:23
User entered 'Venous Thromboembolism'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '07 Dec 2020'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered empty.	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57



**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 23:19:57

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US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 18:55:42
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	17 Mar 2021 14:11:26
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	17 Mar 2021 14:11:26
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:53
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	12 Jan 2021 18:55:42
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 18:55:42
User entered empty.	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered empty.	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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. ' canceled (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:59:48
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)	14 Dec 2020 19:26:51
User entered empty.	System	09 Dec 2020 23:19:57

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'Grade 4 (Grade 4)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'Yes (Y)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '0'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '0'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Per CDM: please update the hospital discharge date once the patient is discharged.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 04:28:54
Query 'Per CDM: please update the hospital discharge date once the patient is discharged.' answered with 'done' (Site from DM).	Kimberly Mueller (b) (4)	17 Mar 2021 14:10:59
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:53
User opened query 'Per CDM: please update the hospital discharge date once the patient is discharged.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:10:27
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 09:09:22
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient is still in hospital' (Site from System).	Jessica Satorie (b) (4)	09 Dec 2020 23:20:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Dec 2020 23:19:57
User entered '1'	Jessica Satorie (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '07 Dec 2020'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 16:36:25
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Medical records were sent on 19APR2021' (Site from Safety).	Jessica Satorie (b) (4)	26 Apr 2021 19:03:17
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 05:30:57
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 18:55:42
User entered empty.	Jessica Satorie (b) (4)	09 Dec 2020 23:19:57

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'No (N)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered empty.	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '0'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '0'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '0'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered 'Not Related (NOT RELATED)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm or clarify assessment of "Not Applicable" in regards to event relatedness to study procedure.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Brandon Essink (b) (4)	29 Mar 2021 13:23:59 29 Mar 2021 04:42:27
Query 'PV Query: Please confirm or clarify assessment of "Not Applicable" in regards to event relatedness to study procedure.' answered with 'corrected' (Site from Safety). DataPoint Un-verified.	Kimberly Mueller (b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:20:45 27 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:20:12
User opened query 'PV Query: Please confirm or clarify assessment of "Not Applicable" in regards to event relatedness to study procedure.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 15:00:35 11 Mar 2021 19:24:53
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Satorie (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 04 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 13:24:02
Query 'PV Query: As the last dose of mRNA-1273 was given on 04 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'done' (Site from Safety).	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 04 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	Kimberly Mueller (b) (4)	27 Mar 2021 20:21:17
User closed query 'PV Query: Please confirm or clarify assessment of "Not Applicable" in regards to event relatedness to study procedure.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please confirm or clarify assessment of "Not Applicable" in regards to event relatedness to study procedure.' answered with 'changed' (Site from Safety).	Kimberly Mueller (b) (4)	27 Mar 2021 20:20:12
DataPoint Un-verified.	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 15:00:55
User opened query 'PV Query: Please confirm or clarify assessment of "Not Applicable" in regards to event relatedness to study procedure.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 16:03:35
User entered 'Not Applicable (NOT APPLICABLE)'	Kimberly Mueller (b) (4)	17 Mar 2021 14:15:43
	(b) (4)	
	Kimberly Mueller (b) (4)	17 Mar 2021 14:11:26
	(b) (4)	
	Kimberly Mueller (b) (4)	17 Mar 2021 14:11:26
	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 19:24:53
	(b) (4), (b) (6)	14 Dec 2020 19:26:03
	Jessica Satorie (b) (4)	09 Dec 2020 23:19:57
	(b) (4)	

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Generated On: 09 Jun 2021 14:49:23

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered '0'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 04:35:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'see xarelto' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	17 Mar 2021 14:16:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:53
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 07:53:57
User entered '1'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV query: Thank you for providing concomitant medications. Con med Xarelto has a start date of 01 Dec, prior to event onset but the indication is for venous thromboembolism. If this is for treatment of the event, please update date appropriately (event onset was 07 Dec). Also, please add iron Venofer x2 doses to concomitant medication eCRF.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 13:24:09
Query 'PV query: Thank you for providing concomitant medications. Con med Xarelto has a start date of 01 Dec, prior to event onset but the indication is for venous thromboembolism. If this is for treatment of the event, please update date appropriately (event onset was 07 Dec). Also, please add iron Venofer x2 doses to concomitant medication eCRF.' answered with 'corrected' (Site from Safety).	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User opened query 'PV query: Thank you for providing concomitant medications. Con med Xarelto has a start date of 01 Dec, prior to event onset but the indication is for venous thromboembolism. If this is for treatment of the event, please update date appropriately (event onset was 07 Dec). Also, please add iron Venofer x2 doses to concomitant medication eCRF.' answered with 'corrected' (Site from Safety).	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:34:39
User opened query 'PV query: Thank you for providing concomitant medications. Con med Xarelto has a start date of 01 Dec, prior to event onset but the indication is for venous thromboembolism. If this is for treatment of the event, please update date appropriately (event onset was 07 Dec). Also, please add iron Venofer x2 doses to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:02:25
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)	18 Mar 2021 04:36:22
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 'see doppler of left leg' (Site from DM).	Kimberly Mueller (b) (4)	17 Mar 2021 14:16:39
User entered '1' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	17 Mar 2021 14:13:21

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Kimberly Mueller (b) (4)	17 Mar 2021 14:13:07
User entered '0' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Kimberly Mueller (b) (4)	17 Mar 2021 14:13:07
	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 19:24:53
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 Jan 2021 07:53:59
User entered '1'	Jessica Satorie (b) (4)	09 Dec 2020 23:19:57
	(b) (4)	



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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'PV Query: As date of end of reaction/event was updated to 12 Dec 2020, please consider updating event outcome to recovered.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:03:51
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)	18 Mar 2021 16:03:47
Query 'PV Query: As date of end of reaction/event was updated to 12 Dec 2020, please consider updating event outcome to recovered.' answered with 'done' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	17 Mar 2021 14:16:52
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 'done' (Site from Safety).	Kimberly Mueller (b) (4) (b) (4)	17 Mar 2021 14:16:46
DataPoint Un-verified.	Kimberly Mueller (b) (4) (b) (4)	17 Mar 2021 14:11:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	17 Mar 2021 14:11:26
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:53
User opened query 'PV Query: As date of end of reaction/event was updated to 12 Dec 2020, please consider updating event outcome to recovered.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 14:34:07
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)	14 Dec 2020 19:21:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:24:53
User entered empty.	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

US3002131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Thank you for your recent response. However, please note that records sent on 19Apr2021 were for a different event. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'no other records available at this time' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	03 May 2021 21:16:17
User opened query 'PV Query: Thank you for your recent response. However, please note that records sent on 19Apr2021 were for a different event. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:00:54
User closed query 'Per DM CLR: SAE Narrative = Shortness of breath and Pulmonary Embolism. Review if these are to be recorded as a separate AE entry. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 09:05:47
User closed query 'PV Query: Per narrative subject had an uterine fibroid that required an ablation during this hospitalization. Please consider if this meet criteria to report separate AE.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 16:35:17
Query 'Per DM CLR: SAE Narrative = Shortness of breath and Pulmonary Embolism. Review if these are to be recorded as a separate AE entry. Else, clarify. ' answered with 'Shortness of breath and pulmonary embolism are symptoms of the venous thromboembolism' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	26 Apr 2021 19:10:04
Query 'PV Query: Per narrative subject had an uterine fibroid that required an ablation during this hospitalization. Please consider if this meet criteria to report separate AE.' answered with 'Uterine fibroid is documented as and AE. Does not meet SAE criteria ' (Site from Safety).	Jessica Satorie (b) (4) (b) (4)	26 Apr 2021 19:05:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per narrative subject had an uterine fibroid that required an ablation during this hospitalization. Please consider if this meet criteria to report separate AE.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 05:31:34
User opened query 'Per DM CLR: SAE Narrative = Shortness of breath and Pulmonary Embolism. Review if these are to be recorded as a separate AE entry. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 13:43:29
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 13:24:14
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'unable to attain as yet. Information from query copied and will upload if record becomes available.' (Site from Safety).	Kimberly Mueller (b) (4)	27 Mar 2021 20:47:10
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 16:03:55
User closed query 'Per DM CLR: SAE Narrative = DOPPLER OF HER RIGHT LEG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 04:36:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = DOPPLER OF HER RIGHT LEG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Kimberly Mueller (b) (4)	17 Mar 2021 14:37:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'done' (Site from Safety).	Kimberly Mueller (b) (4)	17 Mar 2021 14:37:09
User entered 'PATIENT STATED SHE WAS HAVING SHORTNESS OF BREATH ON 07DEC2020. PATIENT WENT TO THE ER. THEY DID A DOPPLER OF HER RIGHT LEG AND FOUND A DVT and ct scan found PULMONARY EMBOLISMs and she was admitted to hospital. Hgb was 6.0 She did not have blood transfusion, but received iron venofer x 2 doses. Subject also reported heavy menstrual bleeding over several months and was found to have a large uterine fibroid. She had uterine ablation and then was started on XARELTO 20 mg daily which she continues.' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	17 Mar 2021 14:37:03
DataPoint Un-verified.	Kimberly Mueller (b) (4)	17 Mar 2021 14:13:07
User entered 'PATIENT STATED SHE WAS HAVING SHORTNESS OF BREATH ON 07DEC2020. PATIENT WENT TO THE ER, THEY DID A DOPPLER OF HER RIGHT LEG AND FOUND A BLOOD CLOT AS WELL AS PULMONARY EMBOLISM. PATIENT STATES SHE WAS ADMITTED AND IS GETTING BETTER. Subject started on Xarelto.' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	17 Mar 2021 14:13:07
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = DOPPLER OF HER RIGHT LEG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 04:41:24
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 19:22:27
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 19:22:03
User entered 'Patient stated she was having shortness of breath on 07DEC2020. Patient went to the ER, they did a doppler of her Right leg and found a blood clot as well as pulmonary embolism. Patient states she was admitted and is getting better.'	Jessica Satorie (b) (4) (b) (4)	09 Dec 2020 23:19:57

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 23:19:57

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**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 23:19:57

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**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 23:19:57

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US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Mar 2021 22:36:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 22:36:55
Data point term sent to Coder	System	11 Mar 2021 22:35:41
User entered 'Hypertension'	(b) (4), (b) (6)	11 Mar 2021 22:35:03

US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	11 Mar 2021 22:35:12
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 22:35:12
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	11 Mar 2021 22:35:03
User entered '01 Dec 2021'	(b) (4), (b) (6)	11 Mar 2021 22:35:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:23**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 22:35:03

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**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:38:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	27 Mar 2021 20:38:43
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	27 Mar 2021 20:37:33
User entered empty; reason for change Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:37:33
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	11 Mar 2021 22:35:24
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	11 Mar 2021 22:35:24
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	11 Mar 2021 22:35:12
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 22:35:12
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	11 Mar 2021 22:35:03
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	11 Mar 2021 22:35:03
User entered '12 Dec 2021'	(b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:23**

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 22:35:03

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US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

US3002131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

Death

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

None

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:37:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 22:35:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	11 Mar 2021 22:35:03

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:23

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:35:03

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 22:35:03

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**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 22:35:03

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US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 22:38:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 22:38:05
Data point term sent to Coder	System	11 Mar 2021 22:36:42
User entered 'Anemia'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

*Start date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '01 Dec 2020'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User entered empty.	System	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '12 Dec 2020'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User entered empty.	System	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27



US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '1'	(b) (4), (b) (6)	11 Mar 2021 22:36:27



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

US3002131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:36:27

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User entered '0'	System	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33
User entered '0'	System	11 Mar 2021 22:36:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:30:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroid - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 21:22:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 21:22:12
Data point term sent to Coder	System	30 Mar 2021 21:21:22
Coding entries removed.	Kimberly Mueller (b) (4)	30 Mar 2021 21:21:00
Signature has been broken.	Kimberly Mueller (b) (4)	30 Mar 2021 21:21:00
User entered 'uterine fibroid' reason for change:	Kimberly Mueller (b) (4)	30 Mar 2021 21:21:00
Data Entry Error	(b) (4)	
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 22:38:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 22:38:06
Data point term sent to Coder	System	11 Mar 2021 22:37:47
User entered 'Menorrhagia'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '30 Sep 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:41:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Mar 2021 20:40:56
User entered '05 Sep 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:40:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Mar 2021 20:40:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Mar 2021 20:40:44
User entered 'un Sep 2020' (non-conformant).	Kimberly Mueller (b) (4)	27 Mar 2021 20:40:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Mar 2021 22:37:12
User entered 'un Dec 2020' (non-conformant).	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Mar 2021 20:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Mar 2021 20:40:56
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User entered empty.	System	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:37:12



US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '13 Jan 2021'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	27 Mar 2021 20:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Mar 2021 20:40:56
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User entered empty.	System	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Mar 2021 20:40:44
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	System	27 Mar 2021 20:40:44
User opened query 'Data is required. Please complete.' (Site from System).	Kimberly Mueller (b) (4)	27 Mar 2021 20:40:44
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12



US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Mar 2021 20:40:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	27 Mar 2021 20:40:44
User opened query 'Data is required. Please complete.' (Site from System).	Kimberly Mueller (b) (4)	11 Mar 2021 22:37:12
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 22:37:12



US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Mar 2021 20:40:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	27 Mar 2021 20:40:44
User opened query 'Data is required. Please complete.' (Site from System).	Kimberly Mueller (b) (4)	11 Mar 2021 22:37:12
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '1'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User signature succeeded.	Brandon Essink (b) (4)	31 Mar 2021 20:30:23
Signature has been broken.	Kimberly Mueller (b) (4)	30 Mar 2021 21:21:00
User entered empty; reason for change Data Entry Error	Kimberly Mueller (b) (4)	30 Mar 2021 21:21:00
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Caused by large uterine fibroid' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:45:35
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:37:12



**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User entered '0'	System	11 Mar 2021 22:37:12

US3002131

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:49:23

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39
User entered '1'	System	11 Mar 2021 22:37:12

**US3002131**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:39

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:49:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:20
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:37:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 22:37:23
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:16:47

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Mar 2021 22:40:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 22:40:03
Data point term sent to Coder	System	11 Mar 2021 22:38:48
User entered 'Amlodipine'	(b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '5'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07



US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07



US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The corresponding MH has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	30 Mar 2021 10:36:16
Query 'Per DM CLR: The corresponding MH has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'corresponding AE corrected to ongoing' (Site from DM).	Brandon Essink (b) (4) (b) (4) Kimberly Mueller (b) (4) (b) (4)	29 Mar 2021 04:42:27 27 Mar 2021 20:45:10
User opened query 'Per DM CLR: The corresponding MH has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:07

**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 22:38:07

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**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 22:38:07

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**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Mar 2021 22:38:07

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US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE, PRODUCTSYNONYM: IRON SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	27 Mar 2021 20:38:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Mar 2021 20:38:22
Data point term sent to Coder	System	27 Mar 2021 20:37:10
Coding entries removed.	Kimberly Mueller (b) (4)	27 Mar 2021 20:36:10
Coding entries removed.	Kimberly Mueller (b) (4)	27 Mar 2021 20:36:10
User entered 'IRON sulfate' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:36:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Mar 2021 22:40:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Mar 2021 22:40:04
Data point term sent to Coder	System	11 Mar 2021 22:38:50
User entered 'Iron'	(b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:36:21
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:38:32



US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered 'ANEMIA prophylaxis' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:36:10
	(b) (4)	
User entered 'Anemia'	(b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '325'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32



US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered '11 Dec 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:36:10
	(b) (4)	
User entered '01 Dec 2020'	(b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CLR re-query: Response noted; however, no update has been made. Kindly review and update Con Med page as appropriate. Otherwise clarify. Thank you.  ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 11:48:24
Query 'Per CDM CLR re-query: Response noted; however, no update has been made. Kindly review and update Con Med page as appropriate. Otherwise clarify. Thank you.	Kimberly Mueller (b) (4)	16 Apr 2021 15:54:33
' answered with 'this con med is ongoing' (Site from DM).	(b) (4)	
User opened query 'Per CDM CLR re-query: Response noted; however, no update has been made. Kindly review and update Con Med page as appropriate. Otherwise clarify. Thank you.	(b) (4), (b) (6)	01 Apr 2021 04:22:11
' (Site from DM).		
User closed query 'Per DM CLR: The corresponding MH has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	01 Apr 2021 04:22:06
' (Site from DM).		
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
Query 'Per DM CLR: The corresponding MH has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.	(b) (4)	
' answered with 'corrected' (Site from DM).	Kimberly Mueller (b) (4)	27 Mar 2021 20:36:15
User opened query 'Per DM CLR: The corresponding MH has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:46:40
Data hard unlocked.	(b) (4), (b) (6)	17 Mar 2021 05:46:35

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	17 Mar 2021 05:46:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:38:32

**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	11 Mar 2021 22:38:32

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**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 22:38:32

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**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Mar 2021 22:38:32

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US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Mar 2021 20:36:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Mar 2021 20:36:21
Data point term sent to Coder Coding entries removed.	System	27 Mar 2021 20:36:09
	Kimberly Mueller (b) (4)	27 Mar 2021 20:35:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 14:17:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 14:17:54
Data point term sent to Coder Coding entries removed.	System	17 Mar 2021 14:16:41
	Kimberly Mueller (b) (4)	17 Mar 2021 14:16:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Mar 2021 22:40:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Mar 2021 22:40:55
Data point term sent to Coder	System	11 Mar 2021 22:39:50

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Xarelto'	(b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:35:16
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'VENOUS THROMBOEMBOLISM prevention' reason for change: Data Entry Error	(b) (4) Kimberly Mueller (b) (4)	27 Mar 2021 20:35:16
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:16:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 14:16:05
User entered 'venous thromboembolism' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	17 Mar 2021 14:16:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	11 Mar 2021 22:39:07
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '20'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07



US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
	(b) (4)	
User entered '12 Dec 2020' reason for change: Data Entry Error	Kimberly Mueller (b) (4)	27 Mar 2021 20:35:04
	(b) (4)	
User entered '01 Dec 2020'	(b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07



US3002131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:07

**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 22:39:07

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**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 22:39:07

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**US3002131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Mar 2021 22:39:07

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US3002131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:49:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:58:20
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:39:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 22:39:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:02:03

US3002131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:23

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:40:15

US3002131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'Uterine ablation'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:40:15

**US3002131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:40:15



US3002131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:23

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 22:40:15

**US3002131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:32
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 19:57:11
User entered '07 Dec 2020'	(b) (4) Kimberly Mueller (b) (4)	17 Mar 2021 14:14:59

**US3002131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:32
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 19:57:11
User entered 'doppler of left leg'	(b) (4) Kimberly Mueller (b) (4)	17 Mar 2021 14:14:59

**US3002131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:32
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 19:57:11
User entered 'Adverse Event (AE)'	(b) (4) Kimberly Mueller (b) (4)	17 Mar 2021 14:14:59

US3002131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:23

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:32
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 19:57:11
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	17 Mar 2021 14:14:59
	(b) (4)	

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'USA-US005-2020-MRNA-1273-P301000012'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32



US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Brandon'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Essink'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '3319 N 107th'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Omaha'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '68134'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered 'US'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 16:38:12
User entered '4'	System	29 Mar 2021 13:24:43
User entered '3'	System	18 Mar 2021 16:05:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
	(b) (4)	
User entered '2'	System	13 Jan 2021 16:40:19
User entered '1'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'USA-US005-2020-MRNA-1273-P301000012'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Brandon'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Essink'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '3319 N 107th'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Omaha'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '68134'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered 'US'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 16:38:12
User entered '4'	System	29 Mar 2021 13:24:43
User entered '3'	System	18 Mar 2021 16:05:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
	(b) (4)	
User entered '2'	System	13 Jan 2021 16:40:19
User entered '1'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:49:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '10/Dec/2020 17:18'	(b) (4) System	10 Dec 2020 17:18:10

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:49:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered '1'	(b) (4), (b) (6)	10 Dec 2020 17:18:10

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'USA-US005-2020-MRNA-1273-P301000012'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Brandon'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Essink'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '3319 N 107th'	System	10 Dec 2020 17:15:32



US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Omaha'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '68134'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered 'US'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 16:38:12
User entered '4'	System	29 Mar 2021 13:24:43
User entered '3'	System	18 Mar 2021 16:05:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
	(b) (4)	
User entered '2'	System	13 Jan 2021 16:40:19
User entered '1'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:49:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
User entered '13/Jan/2021 11:40'	(b) (4) System	13 Jan 2021 16:40:19

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:49:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered '1'	(b) (4), (b) (6)	13 Jan 2021 16:40:19

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'USA-US005-2020-MRNA-1273-P301000012'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Brandon'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Essink'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '3319 N 107th'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Omaha'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '68134'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered 'US'	System	10 Dec 2020 17:18:10

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 16:38:12
User entered '4'	System	29 Mar 2021 13:24:43
User entered '3'	System	18 Mar 2021 16:05:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
	(b) (4)	
User entered '2'	System	13 Jan 2021 16:40:19
User entered '1'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:49:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 19:57:11
User entered '18/Mar/2021 12:05'	(b) (4) System	18 Mar 2021 16:05:57

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:49:23

**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)	29 Mar 2021 13:24:29
User signature succeeded.	Brandon Essink (b) (4)	18 Mar 2021 19:57:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:05:57

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'USA-US005-2020-MRNA-1273-P301000012'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Brandon'	System	10 Dec 2020 17:15:32



**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Essink'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '3319 N 107th'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Omaha'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '68134'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered 'US'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 16:38:12
User entered '4'	System	29 Mar 2021 13:24:43
User entered '3'	System	18 Mar 2021 16:05:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
	(b) (4)	
User entered '2'	System	13 Jan 2021 16:40:19
User entered '1'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:49:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	30 Mar 2021 12:59:51
User entered '29/Mar/2021 13:24'	(b) (4) System	29 Mar 2021 13:24:43

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:49:23

**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)	27 Apr 2021 16:38:17
User signature succeeded.	Brandon Essink (b) (4)	30 Mar 2021 12:59:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:24:43



US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'USA-US005-2020-MRNA-1273-P301000012'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Yes (Y)'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'No (N)'	System	10 Dec 2020 17:15:32



US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Brandon'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Essink'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '3319 N 107th'	System	10 Dec 2020 17:15:32

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:23

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered 'Omaha'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:17:20
User entered '68134'	System	10 Dec 2020 17:15:32

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:24:06
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:40:23
User entered 'US'	System	10 Dec 2020 17:18:10

**US3002131**

**Folder: SAE USA-US005-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:49:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 16:38:12
User entered '4'	System	29 Mar 2021 13:24:43
User entered '3'	System	18 Mar 2021 16:05:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:03:21
	(b) (4)	
User entered '2'	System	13 Jan 2021 16:40:19
User entered '1'	System	10 Dec 2020 17:18:10

US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:49:23

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	01 May 2021 11:48:52
User entered '27/Apr/2021 12:38'	(b) (4) System	27 Apr 2021 16:38:12



US3002131

Folder: SAE USA-US005-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:49:23

**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.	Brandon Essink (b) (4)	01 May 2021 11:48:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 16:38:17
User entered 'I'	(b) (4), (b) (6)	27 Apr 2021 16:38:12