

US3182025 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:35:54

All time stamps listed in this document are displayed in GMT

US3182025

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:01:49

Generated On: 09 Jun 2021 15:35:54

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[Participant ID](#)

US3182025

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

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US3182025

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 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

US3182025

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
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

US3182025

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Date of Informed Consent (*dd MMM yyyy*) 28 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

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

Was this participant screened previously?

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

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

Enrollment Trigger 1

US3182025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3182025

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

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Were any significant conditions reported?

Yes ☒

No ☐

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US3182025

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	(b) (6) 1990
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)	(b) (6) 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3182025

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Condition	PERENNIAL ALLERGIES
Start date (dd MMM yyyy)	(b) (6) 1990
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)	(b) (6) 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3182025

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Condition	ALLERGY TO APPLES
Start date (dd MMM yyyy)	(b) (6) 1990
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)	(b) (6) 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3182025

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182025

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182025

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3182025

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	08:20 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 08:20
Height ( <i>xxx.x</i> )	162.4 cm
Weight ( <i>xxx.x</i> )	84.3 kg
BMI ( <i>xxx.x</i> )	31.96359 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)	

US3182025

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

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

US3182025

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Date of assessment (dd MMM yyyy) 28 JUL 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



US3182025

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	28 JUL 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3182025

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

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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**

UNEMPLOYED. LIVES IN HIGH RISK COUNTY.

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

**No Risk Identified** True

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

US3182025

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:31:47

Generated On: 09 Jun 2021 15:35:54

<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>	

US3182025

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 142121

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 ☒

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Height	ND - Not Done
Weight	ND - Not Done

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 08:20
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 10:15
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG



US3182025

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

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) \_\_\_\_\_

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

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) 28 JUL 2020

What was the treatment time? (00:00-23:59) 09:40 (24 HR)

Treatment Date and Time (derived) 28 JUL 2020 09:40

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

US3182025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JUL 2020
Collection time (00:00-23:59)	09:25 (24 HR)
Collection date and time (derived)	28 JUL 2020 09:25

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Collection date (dd MMM yyyy)			28 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:19	28 JUL 2020 09:19
Nasopharyngeal Swab 2	No		

US3182025

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

99.4 °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 28 JUL 2020 10:04

PC Open Date & Time 28 JUL 2020 10:00

PC Close Date & Time 28 JUL 2020 12:30

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 JUL 2020 13:25

PC Close Date & Time

29 JUL 2020 11:59



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

99.0 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

29 JUL 2020 18:46

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PC Open Date & Time

29 JUL 2020 12:00

---

PC Close Date & Time

30 JUL 2020 11:59

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US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.6 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

30 JUL 2020 18:54

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PC Open Date & Time

30 JUL 2020 12:00

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PC Close Date & Time

31 JUL 2020 11:59

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US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

31 JUL 2020 16:11

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 21:45

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

02 AUG 2020 19:30

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 13:52

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 10:05

PC Open Date & Time

28 JUL 2020 10:00

PC Close Date & Time

28 JUL 2020 12:30

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 JUL 2020 13:25

PC Close Date & Time

29 JUL 2020 11:59



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 18:47

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 18:55

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 16:11

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 21:44

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 19:29

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 13:51

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**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 ☐

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 10:06
PC Open Date & Time	28 JUL 2020 10:00
PC Close Date & Time	28 JUL 2020 12:30



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**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 ☐

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 JUL 2020 13:25

PC Close Date & Time

29 JUL 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**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 ☒

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 18:47
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

52 of 2755

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 18:55
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**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 ☒

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 16:12
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2755

EAB) (1725)

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:44
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

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 ☒

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 19:29
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2755

EAB) (1725)

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 13:51
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3182025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3182025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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	VISIT2

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:56:17

Generated On: 09 Jun 2021 15:35:54

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	07:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 07:50
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	93 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 18:56:17

Generated On: 09 Jun 2021 15:35:54

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	09:34 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:34
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3182025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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



US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 24 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 08:53 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 08:53

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

US3182025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 AUG 2020
Collection time (00:00-23:59)	08:23 (24 HR)
Collection date and time (derived)	24 AUG 2020 08:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:15	24 AUG 2020 08:15
Nasopharyngeal Swab 2	No		

US3182025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**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

98.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 24 AUG 2020 09:29

PC Open Date & Time 24 AUG 2020 09:13

PC Close Date & Time 24 AUG 2020 11:43

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.8 °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):

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

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

PC Time Stamp 24 AUG 2020 16:10

PC Open Date & Time 24 AUG 2020 12:38

PC Close Date & Time 25 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

102.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

99.1 °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

26 AUG 2020 13:57

---

PC Open Date & Time

26 AUG 2020 12:00

---

PC Close Date & Time

27 AUG 2020 11:59

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US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 18:36

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 18:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 21:24

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:08

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 09:32

PC Open Date & Time

24 AUG 2020 09:13

PC Close Date & Time

24 AUG 2020 11:43

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**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

24 AUG 2020 16:11

PC Open Date & Time

24 AUG 2020 12:38

PC Close Date & Time

25 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 13:56

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 18:35

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 18:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 21:23

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:08

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**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 ☐

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 09:29
PC Open Date & Time	24 AUG 2020 09:13
PC Close Date & Time	24 AUG 2020 11:43

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**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 ☐



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 16:08
PC Open Date & Time	24 AUG 2020 12:38
PC Close Date & Time	25 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**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 ☐

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

		Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 12:01	
PC Open Date & Time	25 AUG 2020 12:00	
PC Close Date & Time	26 AUG 2020 11:59	

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**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 ☒

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 13:57
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**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 ☒

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:35
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2755

EAB) (1725)



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 18:07
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

105 of 2755

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:23
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 2755

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:08
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3182025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:56:15

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3182025

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:56:16

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:56:17

Generated On: 09 Jun 2021 15:35:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 18:56:17

Generated On: 09 Jun 2021 15:35:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 15:19
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:56:17

Generated On: 09 Jun 2021 15:35:54

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3182025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:56:17

Generated On: 09 Jun 2021 15:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	15:28 (24 HR)
Collection date and time (derived)	24 SEP 2020 15:28

US3182025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:56:17

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 SEP 2020 08:02:32

Patient Cloud Open Date & Time

27 SEP 2020 00:01

Patient Cloud Close Date & Time

01 OCT 2020 23:59

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

04 OCT 2020 23:13:33

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

12 OCT 2020 14:56:47

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

26 OCT 2020 08:55:30

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 16:42:31
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 NOV 2020 00:01:56
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 15:01:24

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

19 NOV 2020 09:17:13

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 05:42:37

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 13:07:02
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

10 DEC 2020 12:33:57

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

17 DEC 2020 22:00:50

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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	27 DEC 2020 09:39:57
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 08:28:38

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 JAN 2021 09:51:31
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

15 JAN 2021 04:56:56

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

21 JAN 2021 08:24:44

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 14:46:08

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 16:37:00

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 11:40:27

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 09:06:07
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	True
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	True
Vomiting	True
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 FEB 2021 04:48:49
Patient Cloud Open Date & Time	25 FEB 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
141 of 2755	

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

05 MAR 2021 11:51:16

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 00:02:31

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 18:56:27

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 09:38:27

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 08:12:37

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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

08 APR 2021 19:50:45

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 16:00:41

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:02:26

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

Date and time of submission

29 APR 2021 04:26:15

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59
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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59
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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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10 JAN 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 JAN 2022 00:01

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31 JAN 2022 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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03 MAR 2022 00:01

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07 MAR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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30 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2022 23:59
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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2022 23:59

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

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

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 ☐

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

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

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3182025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3182025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:35:54

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 04:48:55

US3182025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3182025

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

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

Visit date (dd MMM yyyy)	09 FEB 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:52:29

Generated On: 09 Jun 2021 15:35:54

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) \_\_\_\_\_

US3182025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 14:52:29

Generated On: 09 Jun 2021 15:35:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 FEB 2021

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



US3182025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 FEB 2021
Collection time (00:00-23:59)	10:19 (24 HR)
Collection date and time (derived)	09 FEB 2021 10:19

US3182025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 14:47:34

Generated On: 09 Jun 2021 15:35:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182025

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 14:47:34

Generated On: 09 Jun 2021 15:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182025

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

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*

**US3182025**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:35:54**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182025

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:35:54

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

US3182025

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:35:54

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3182025

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

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

Visit date (dd MMM yyyy)	09 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3182025

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 17:43:32

Generated On: 09 Jun 2021 15:35:54

Date of updated informed consent (*dd MMM yyyy*) 09 FEB 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*) 09 FEB 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 \_\_\_\_\_

US3182025

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 FEB 2021
Collection time (00:00-23:59)	10:25 (24 HR)
Collection date and time (derived)	09 FEB 2021 10:25

US3182025

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 FEB 2021
Collection time (00:00 - 23:59)	10:19
Collection Date and Time (derived)	09 FEB 2021 10:19

US3182025

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:01:49

Generated On: 09 Jun 2021 15:35:54

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID	USA-US075-2021-MRNA-1273-P30 1000010
Adverse event	DYSFUNCTIONAL UTERINE BLEEDING
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)	20 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	08 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	325 of 2755

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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SUBJECT UNDERWENT A  
HYSTEROSCOPY WITH D&C  
AND REMOVAL OF IUD ON  
1/7/21 FOR ABNORMAL  
UTERINE BLEEDING  
RESULTING IN SEVERE  
ANEMIA UNRELIEVED WITH  
OCP'S AND DEPO PROVERA ,  
NOW WITH HCT 21 AFTER  
BLOOD TRANSFUSION ONE  
WEEK PRIOR TO SURGERY.  
PELVIC US WAS SIGNIFICANT  
FOR A RETIATED IUD PLACED  
IN ISRAEL 3 YEARS AGO AND  
WITH UNSUCCESSFUL  
IN-OFFICE ATTEMPT AT  
REMOVAL. SURGERY WAS  
UNCOMPLICATED, HOWEVER  
SHE WAS GIVEN 2 UNTIS OF  
PRBC'S INTRAOPERATIVELY. IN  
PACU, SHE COMPLAINED OF  
LIGHTEADEDNESS WITH  
STANDING, DIZZINESS AND  
INABILITY TO STAY AWAKE,  
AS WELL AS LOWER  
ABDOMINAL CRAMPING. SHE  
WAS KEPT OVERNIGHT FOR  
OBSERVATION DUE TO HER  
SYMPTOMS, KNOWN ANEMIA,  
AND RECEIPT OF BLOOD  
TRANSFUSION  
INTRAOPERATIVELY.

---

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)	

---

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US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID

Adverse event

IRON DEFICIENCY ANEMIA

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)

24 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)

06 APR 2021

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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

328 of 2755

EAB) (1725)

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID

Adverse event

VAGINAL YEAST INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 JAN 2021

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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

330 of 2755

EAB) (1725)

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID

Adverse event

THROMBOPHLEBITIS-LEFT  
ARM

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)

28 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)

07 JAN 2021

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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

332 of 2755

EAB) (1725)

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID

Adverse event

ABDOMINAL CRAMPING

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)

13 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)

14 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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

334 of 2755

EAB) (1725)

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID	
Adverse event	NAUSEA
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)	13 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)	14 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

336 of 2755

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID	
Adverse event	DIARRHEA
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)	13 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)	14 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

338 of 2755

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID	
Adverse event	DIZZINESS
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)	07 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

340 of 2755

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID

Adverse event

ABDOMINAL PAIN

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)

28 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)

28 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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

342 of 2755

EAB) (1725)

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

AEID

Adverse event

UNSPECIFIED PAIN

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)

24 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)

24 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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

344 of 2755

EAB) (1725)

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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)	_____

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:01:49

Generated On: 09 Jun 2021 15:35:54

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

Yes ☒

No ☐

---

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

---

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

347 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication FLUTICASONE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

349 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

351 of 2755



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication NON HORMONAL IUD

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

353 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	07 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication NUVARING

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input checked="" 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)	15 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication FEVER/HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

357 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication EXCEDRIN (ACETAMINOPHEN,  
ASPIRIN, AND CAFFEINE)

Prophylaxis Yes ☐  
No ☒

Indication FEVER/HEADACHE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

359 of 2755



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)		24 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

361 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)		08 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN SECONDARY TO  
DYSFUNCTIONAL UTERINE  
BLEEDING

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

363 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)		08 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication DIFLUCAN

Prophylaxis Yes ☐  
No ☒

Indication UTERINE YEAST INFECTION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

365 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)	15 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication OMNIPAQUE 350

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL CRAMPING

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

367 of 2755

EAB) (1725)



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" 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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" 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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication KETOROLAC

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL CRAMPING

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

371 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" 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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL CRAMPING

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

373 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication ESTROGEN

Prophylaxis Yes ☐  
No ☒

Indication DYSFUNCTIONAL UTERINE BLEEDING

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 2755



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication IRON

Prophylaxis Yes ☐  
No ☒

Indication DYSFUNCTIONAL UTERINE  
BLEEDING/ANEMIA

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

377 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication PACKED RED BLOOD CELLS

Prophylaxis Yes ☐  
No ☒

Indication DYSFUNCTIONAL UTERINE  
BLEEDING/ANEMIA

Dose per administration 1

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

If dose unit is Other, specify UNIT

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication PACKED RED BLOOD CELLS

Prophylaxis Yes ☐  
No ☒

Indication DYSFUNCTIONAL UTERINE  
BLEEDING/ANEMIA

Dose per administration 2

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

381 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

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

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication CETAZOLIN

Prophylaxis Yes ☐  
No ☒

Indication THROMBOPHLEBITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

383 of 2755



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	29 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐  
No ☒

Indication IRON DEFICIENCY ANEMIA

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 ☐

PRODUCTION RELEASE (v12.003

385 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐  
No ☒

Indication THROMBOPHLEBITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

387 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication HYDROMORPHINE

Prophylaxis Yes ☐  
No ☒

Indication PAIN SECONDARY TO D&C

Dose per administration 0.5

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

EVERY 15 MINUTES X3

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

PRODUCTION RELEASE (v12.003

389 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN SECONDARY TO D&C

Dose per administration 400

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

EVERY 6 HOURS AS NEEDED

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

PRODUCTION RELEASE (v12.003

391 of 2755

EAB) (1725)



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication PROMETHAZINE

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA

Dose per administration 12.5

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 ☐

PRODUCTION RELEASE (v12.003

393 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	07 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication IV CONTRAST (UNKNOWN)

Prophylaxis Yes ☐  
No ☒

Indication FOR CT SCAN

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

395 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" 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)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication ODANSETRON

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

397 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication KETOROLAC

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 15

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

399 of 2755

EAB) (1725)



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

401 of 2755

EAB) (1725)

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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)		28 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication ESTROGEN

Prophylaxis Yes ☐  
No ☒

Indication DYSFUNCTIONAL UTERINE BLEEDING

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

403 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication IRON

Prophylaxis Yes ☐  
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration UNKNOWN

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

405 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

Name of Medication PACKED RED BLOOD CELLS

Prophylaxis Yes ☐  
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNIT

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

407 of 2755

EAB) (1725)



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 20:00:00

Generated On: 09 Jun 2021 15:35:54

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:01:50

Generated On: 09 Jun 2021 15:35:54

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3182025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Mar 2021 14:47:34

Generated On: 09 Jun 2021 15:35:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 JAN 2021	DILATION AND CURETTAGE	Adverse Event	

US3182025

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:35:54

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 ☐

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 12:18:55

Generated On: 09 Jun 2021 15:35:54

SAEID	USA-US075-2021-MRNA-1273-P301000010
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 12:18:55

Generated On: 09 Jun 2021 15:35:54

SAEID	USA-US075-2021-MRNA-1273-P301000010
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/MAR/2021 11:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 12:18:55

Generated On: 09 Jun 2021 15:35:54

SAEID	USA-US075-2021-MRNA-1273-P301000010
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/MAR/2021 08:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 12:18:55

Generated On: 09 Jun 2021 15:35:54

SAEID	USA-US075-2021-MRNA-1273-P301000010
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 17:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3182025 (Prod: Rapid Medical Research Inc - ERN-PPDS)

**US3182025**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:35:54**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'US3182025'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 12:44:33

US3182025

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:48:18
	(b) (4)	

US3182025

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 12:44:34

US3182025

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[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 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Clinic (Clinic)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	28 Jul 2020 13:48:18

**US3182025**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:35:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'SCRN'	System	28 Jul 2020 13:48:18

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 12:44:35

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '30'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:02:16



**US3182025**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:35:54**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'YEARS'	System	29 Jul 2020 14:02:16

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '30'	System	28 Jul 2020 13:48:47

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Female (F)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:02:16

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:02:16

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'I'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:02:16
	(b) (4)	

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:02:16
	(b) (4)	

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:02:16
	(b) (4)	

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:02:16



US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:02:16

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:02:16
	(b) (4)	

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:02:16
	(b) (4)	

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:02:16
	(b) (4)	

US3182025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:02:16
	(b) (4)	

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '28 Jul 2020'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:48:47
	(b) (4)	

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'Jul 2020'	System	28 Jul 2020 13:48:47

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '2020'	System	28 Jul 2020 13:48:47



US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Amendment 1 (1)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	28 Jul 2020 13:48:47

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:48:47
	(b) (4)	

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:48:47
	(b) (4)	

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:48:47
	(b) (4)	

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:48:47
	(b) (4)	

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 12:44:34

US3182025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'I'	System	28 Jul 2020 13:48:59

US3182025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:35:54

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:48:59
	(b) (4)	



US3182025

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:35:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:02:52

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 21:41:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:41:03
Data point term sent to Coder	System	29 Jul 2020 14:04:12
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:03:12

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
	(b) (4)	
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		30 Jul 2020 11:47:46
User entered (b) (6) 1990' reason for change: DataEntry Error	Cassie Uminski (b) (4)	30 Jul 2020 11:47:46
	(b) (4)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	29 Jul 2020 14:03:12
User entered 'un UNK 1990'	Cassie Uminski (b) (4)	29 Jul 2020 14:03:12
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:03:12

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:03:12

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:03:12
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:03:12

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered (b) (6) 1990'	System	30 Jul 2020 11:47:46
User entered (b) (6) 1990'	System	29 Jul 2020 14:03:12



US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '1990'	System	29 Jul 2020 14:03:12

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:03:12

US3182025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:03:12

US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Perennial allergy, LLT: Perennial allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:20
Data point term sent to Coder	System	29 Jul 2020 14:04:11
User entered 'Perennial Allergies'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:03:55

US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
	(b) (4)	
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		30 Jul 2020 11:47:55
User entered (b) (6) 1990' reason for change: DataEntry Error	Cassie Uminski (b) (4)	30 Jul 2020 11:47:55
	(b) (4)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	29 Jul 2020 14:03:55
User entered 'un UNK 1990'	Cassie Uminski (b) (4)	29 Jul 2020 14:03:55
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:03:55
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:03:55

US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:03:55
	(b) (4)	



US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:03:55

US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered (b) (6) 1990'	System	30 Jul 2020 11:47:55
User entered (b) (6) 1990'	System	29 Jul 2020 14:03:55

US3182025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '1990'	System	29 Jul 2020 14:03:55

**US3182025**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:03:55

**US3182025**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:03:55

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 23:38:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 23:38:09
Data point term sent to Coder	System	29 Jul 2020 14:05:13
User entered 'Allergy to apples'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:04:15

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
	(b) (4)	
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		30 Jul 2020 11:48:05
User entered (b) (6) 1990' reason for change: DataEntry Error	Cassie Uminski (b) (4)	30 Jul 2020 11:48:05
	(b) (4)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	29 Jul 2020 14:04:15
User entered 'un UNK 1990'	Cassie Uminski (b) (4)	29 Jul 2020 14:04:15
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:04:15



US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:04:15

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:04:15
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:04:15
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered (b) (6) 1990'	System	30 Jul 2020 11:48:05
User entered (b) (6) 1990'	System	29 Jul 2020 14:04:15

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '1990'	System	29 Jul 2020 14:04:15

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:04:15

US3182025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:04:15

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:32
Data point term sent to Coder	System	29 Jul 2020 14:06:14
User entered 'Presbyopia'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:05:19



US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'un UNK 2000'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:05:19

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:05:19

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:05:19

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:05:19
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:05:19
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'Jan 2000'	System	29 Jul 2020 14:05:19

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '2000'	System	29 Jul 2020 14:05:19

US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:05:19



US3182025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:05:19

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:28
Data point term sent to Coder	System	29 Jul 2020 14:06:15
User entered 'Depression'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:05:50

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'un UNK 2010'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:05:50

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:05:50
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:05:50

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:05:50
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:05:50
	(b) (4)	

**US3182025**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'Jan 2010'	System	29 Jul 2020 14:05:50



US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '2010'	System	29 Jul 2020 14:05:50

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:05:50

US3182025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:05:50

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:47
Data point term sent to Coder	System	29 Jul 2020 14:06:15
User entered 'Anxiety'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:06:05

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'un UNK 2010'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:06:05
	(b) (4)	

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:06:05

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:06:05

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:06:05
	(b) (4)	



US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:06:05

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'Jan 2010'	System	29 Jul 2020 14:06:05

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '2010'	System	29 Jul 2020 14:06:05

**US3182025**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:06:05

US3182025

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:06:05

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
	(b) (4)	

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '28 Jul 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:08:21

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '08:20'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
	(b) (4)	



US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered '28 Jul 2020 08:20'	System	29 Jul 2020 14:08:21

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '162.4' cm	(b) (4) Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
DataPoint set to visible.	(b) (4) System	28 Jul 2020 13:48:59

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '84.3' kg	(b) (4) Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
DataPoint set to visible.	(b) (4) System	28 Jul 2020 13:48:59

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
Amendment Manager: User entered '31.96359'	System	16 Sep 2020 23:37:12
User entered '32.0'	System	29 Jul 2020 14:08:21
DataPoint set to visible.	System	28 Jul 2020 13:48:59

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'kg/m2'	System	29 Jul 2020 14:08:21
DataPoint set to visible.	System	28 Jul 2020 13:48:59

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:05
User entered '98.9' F	Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
	(b) (4)	

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 02:45:56
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	24 Sep 2020 18:32:14
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	24 Sep 2020 18:32:08
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 16:21:51
User entered 'Other (Other)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 01:53:05
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:08:21

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Sep 2020 18:32:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	05 Aug 2020 01:53:05
User entered empty.	(b) (4) Cassie Uminski (b) (4)	29 Jul 2020 14:08:21



US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:05
User entered '73'	Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
	(b) (4)	

**US3182025**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:35:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'bpm'	System	29 Jul 2020 14:08:21

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:05
User entered '14'	Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
	(b) (4)	

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'breaths/min'	System	29 Jul 2020 14:08:21

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:05
User entered '110'	Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
	(b) (4)	

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'mmHg'	System	29 Jul 2020 14:08:21

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:05
User entered '76'	Cassie Uminski (b) (4)	29 Jul 2020 14:08:21
	(b) (4)	

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered 'mmHg'	System	29 Jul 2020 14:08:21



US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33

US3182025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33

US3182025

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:08:50
	(b) (4)	

US3182025

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
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)	27 Aug 2020 12:37:58
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 13:04:59
User entered '28 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:08:50

US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '28 Jul 2020'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:21
	(b) (4)	

US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:09:21

US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:21
	(b) (4)	

US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:21
	(b) (4)	



US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:21
	(b) (4)	

US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:21
	(b) (4)	

US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:21
	(b) (4)	

US3182025

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:54

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:21
	(b) (4)	

US3182025

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:34
	(b) (4)	

US3182025

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '28 Jul 2020'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:34
	(b) (4)	

US3182025

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Urine (URINE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:09:34

US3182025

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Negative (NEGATIVE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:09:34



US3182025

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:34
	(b) (4)	

**US3182025**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:35:54**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:34
	(b) (4)	

US3182025

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:09:34
	(b) (4)	

**US3182025**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:35:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User entered empty.	System	29 Jul 2020 14:09:34

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	



US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	



US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'Unemployed. Lives in high risk county.'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered 'I'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

**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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

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)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:10:26

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	

US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	



US3182025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:31:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:10:26
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:49:18
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '28 Jul 2020'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:49:18
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Clinic (Clinic)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	28 Jul 2020 13:49:18

US3182025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'VISIT1'	System	28 Jul 2020 13:49:18

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 13:34:22

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:06:05
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:06:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 13:34:22
User entered '142121' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 13:34:22

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:29:30
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).		07 Oct 2020 18:29:29
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Subject not at risk, unable to make updates for this in endpoint' (Site from System).	Cassie Uminski (b) (4) (b) (4)	02 Oct 2020 18:43:57
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 20:58:07
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Unable to update in endpoint, subject not at risk' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	30 Sep 2020 18:38:47
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 17:18:26
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' canceled (Site from System).		30 Sep 2020 17:18:17
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	29 Jul 2020 14:11:11
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 13:34:22



US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

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)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:11:11
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

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)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:11:11

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:11:11
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:11:11
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:11:11
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:22
User entered '162.4' cm	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:22
User entered '84.3' kg	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:22
User entered '162.4' cm	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	



US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:22
User entered '84.3' kg	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '28 Jul 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '08:20'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '28 Jul 2020 08:20'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '98.9' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Oral (Oral)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	



US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '73'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'bpm'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '14'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'breaths/min'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '110'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '76'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08



US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 01:53:22
User entered '162.4' cm	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Aug 2020 01:53:22
User entered '84.3' kg	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '28 Jul 2020'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
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)	04 Aug 2020 18:21:54
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, post dose vital signs are to be collected at least 30 minutes after dose administration.' (Site from System).	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:55
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).		29 Jul 2020 14:13:08
User entered '10:15'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '28 Jul 2020 10:15'	System	29 Jul 2020 14:13:08



US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '97.5' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Oral (Oral)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '72'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'bpm'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '14'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'breaths/min'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '112'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	



US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '74'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:13:08
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	29 Jul 2020 14:13:08

US3182025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 01:53:39
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:14:41
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	05 Aug 2020 01:53:39
User entered '28 Jul 2020'	(b) (4) Cassie Uminski (b) (4)	29 Jul 2020 14:14:41
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 02:32:05
Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:17:26
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:17:21
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test and FSH sample data should be removed from this page. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 13:14:26
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test and FSH sample data should be removed from this page. Please update accordingly.' (Site from DM).		11 Sep 2020 13:14:19
User entered 'Yes (Y)'		09 Sep 2020 17:28:12
	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:14:54

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	25 Sep 2020 12:17:21
User entered '28 Jul 2020'	(b) (4) Cassie Uminski (b) (4)	29 Jul 2020 14:14:54
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	25 Sep 2020 12:17:21
User entered 'Urine (URINE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:14:54



US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	25 Sep 2020 12:17:21
User entered 'Negative (NEGATIVE)'	(b) (4) Cassie Uminski (b) (4)	29 Jul 2020 14:14:54
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	25 Sep 2020 12:17:21
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	29 Jul 2020 14:14:54
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:14:54
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:14:54
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered empty.	System	29 Jul 2020 14:14:54

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:49:48
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:49:48
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:49:48
	(b) (4)	



US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 13:49:48

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '28 Jul 2020'	(b) (4) Brooke Glivar (b) (4) (b) (4)	28 Jul 2020 13:49:48

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '09:40'	(b) (4)	
	Brooke Glivar (b) (4)	28 Jul 2020 13:49:48
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '28 Jul 2020 09:40'	System	28 Jul 2020 13:49:48

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	28 Jul 2020 13:49:48

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'ONCE'	System	28 Jul 2020 13:49:48

US3182025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 13:49:48

US3182025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:41



US3182025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '28 Jul 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:41

US3182025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '09:25'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:15:41
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '28 Jul 2020 09:25'	System	29 Jul 2020 14:15:41

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '28 Jul 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:17

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:17

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:17

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '09:19'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:15:17
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '28 Jul 2020 09:19'	System	29 Jul 2020 14:15:17



US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:17

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:15:17
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:17

US3182025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered empty.	System	29 Jul 2020 14:15:17

US3182025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:15:50
	(b) (4)	

US3182025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'I'	System	29 Jul 2020 14:15:50

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:03:09', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c9789d18-2cb7-415d-be74-02cffeafb038'	System	28 Jul 2020 14:04:14
User entered 'Yes (Y)'	System	28 Jul 2020 14:04:14



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:04:05', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c9789d18-2cb7-415d-be74-02cffeafb038' User entered '99.4'	System	28 Jul 2020 14:04:14
	System	28 Jul 2020 14:04:14

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:04:09', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c9789d18-2cb7-415d-be74-02cffeafb038'	System	28 Jul 2020 14:04:14
User entered 'No (N)'	System	28 Jul 2020 14:04:14

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:04:13', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c9789d18-2cb7-415d-be74-02cffeafb038'	System	28 Jul 2020 14:04:14
User entered '28 Jul 2020 10:04'	System	28 Jul 2020 14:04:14

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 10:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 12:30'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 13:25'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 2'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:15', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0af9fc77-e737-46c7-a3f4-7129747872dd' User entered 'Yes (Y)'	System	29 Jul 2020 22:46:41
	System	29 Jul 2020 22:46:41



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:25', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0af9fc77-e737-46c7-a3f4-7129747872dd' User entered '99.0'	System	29 Jul 2020 22:46:41
	System	29 Jul 2020 22:46:41

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:28', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0af9fc77-e737-46c7-a3f4-7129747872dd'	System	29 Jul 2020 22:46:41
User entered 'No (N)'	System	29 Jul 2020 22:46:41

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:31', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0af9fc77-e737-46c7-a3f4-7129747872dd' User entered '29 Jul 2020 18:46'	System	29 Jul 2020 22:46:41
	System	29 Jul 2020 22:46:41

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 3'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:53:34', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2e89a77b-95ef-439d-befc-529e548207f7' User entered 'Yes (Y)'	System	30 Jul 2020 22:54:52
	System	30 Jul 2020 22:54:52

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:54:39', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2e89a77b-95ef-439d-befc-529e548207f7' User entered '98.6'	System	30 Jul 2020 22:54:52
	System	30 Jul 2020 22:54:52



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:52:42', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2e89a77b-95ef-439d-befc-529e548207f7'	System	30 Jul 2020 22:54:52
User entered 'No (N)'	System	30 Jul 2020 22:54:52

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:54:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2e89a77b-95ef-439d-befc-529e548207f7' User entered '30 Jul 2020 18:54'	System	30 Jul 2020 22:54:52
	System	30 Jul 2020 22:54:52

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 4'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:10:32', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f70f3b24-c86e-4d81-a770-5b7d47610cd5' User entered 'Yes (Y)'	System	31 Jul 2020 20:11:56
	System	31 Jul 2020 20:11:56

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f70f3b24-c86e-4d81-a770-5b7d47610cd5' User entered '99.1'	System	31 Jul 2020 20:11:56
	System	31 Jul 2020 20:11:56

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:23', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f70f3b24-c86e-4d81-a770-5b7d47610cd5'	System	31 Jul 2020 20:11:56
User entered 'No (N)'	System	31 Jul 2020 20:11:56



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f70f3b24-c86e-4d81-a770-5b7d47610cd5' User entered '31 Jul 2020 16:11'	System	31 Jul 2020 20:11:56
	System	31 Jul 2020 20:11:56

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 5'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:03', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fe8a2e3c-dbe5-483b-9d25-9eb34c2ce83f' User entered 'Yes (Y)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:45:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fe8a2e3c-dbe5-483b-9d25-9eb34c2ce83f' User entered '98.0'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:45:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fe8a2e3c-dbe5-483b-9d25-9eb34c2ce83f' User entered 'No (N)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:45:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fe8a2e3c-dbe5-483b-9d25-9eb34c2ce83f' User entered '01 Aug 2020 21:45'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 6'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '358873b1-afa1-4465-95d1-bb7664b0d3d2' User entered 'Yes (Y)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:30:35', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '358873b1-afa1-4465-95d1-bb7664b0d3d2' User entered '98.9'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:30:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '358873b1-afa1-4465-95d1-bb7664b0d3d2'	System	24 Aug 2020 13:27:07
User entered 'No (N)'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:30:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '358873b1-afa1-4465-95d1-bb7664b0d3d2' User entered '02 Aug 2020 19:30'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 13:49:48



US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 7'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:26', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9b9616e4-6b94-4347-877b-55bc313df794' User entered 'Yes (Y)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9b9616e4-6b94-4347-877b-55bc313df794' User entered '98.3'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9b9616e4-6b94-4347-877b-55bc313df794'	System	24 Aug 2020 13:27:09
User entered 'No (N)'	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:52:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9b9616e4-6b94-4347-877b-55bc313df794'	System	24 Aug 2020 13:27:09
User entered '03 Aug 2020 13:52'	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 13:49:48



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:04:19', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51ea59b7-8f8c-4798-89bb-9949a89f6005'	System	28 Jul 2020 14:05:21
User entered 'None (1)'	System	28 Jul 2020 14:05:21

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51ea59b7-8f8c-4798-89bb-9949a89f6005' User entered 'No (N)'	System	28 Jul 2020 14:05:21
	System	28 Jul 2020 14:05:21

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:10', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51ea59b7-8f8c-4798-89bb-9949a89f6005' User entered 'No (N)'	System	28 Jul 2020 14:05:21
	System	28 Jul 2020 14:05:21

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51ea59b7-8f8c-4798-89bb-9949a89f6005'	System	28 Jul 2020 14:05:21
User entered 'None (1)'	System	28 Jul 2020 14:05:21

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:19', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51ea59b7-8f8c-4798-89bb-9949a89f6005' User entered '28 Jul 2020 10:05'	System	28 Jul 2020 14:05:21
	System	28 Jul 2020 14:05:21

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 10:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 12:30'	System	28 Jul 2020 13:49:48



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

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)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 13:25'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 2'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:40', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '3cf4714d-5628-4611-acc5-9bb651e3942b' User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 22:47:24
	System	29 Jul 2020 22:47:24

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:43', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '3cf4714d-5628-4611-acc5-9bb651e3942b' User entered 'No (N)'	System	29 Jul 2020 22:47:24
	System	29 Jul 2020 22:47:24

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '3cf4714d-5628-4611-acc5-9bb651e3942b' User entered 'No (N)'	System	29 Jul 2020 22:47:24
	System	29 Jul 2020 22:47:24

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:46:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '3cf4714d-5628-4611-acc5-9bb651e3942b' User entered 'None (1)'	System	29 Jul 2020 22:47:24
	System	29 Jul 2020 22:47:24

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '3cf4714d-5628-4611-acc5-9bb651e3942b' User entered '29 Jul 2020 18:47'	System	29 Jul 2020 22:47:24
	System	29 Jul 2020 22:47:24



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 3'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:54:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1ba0887c-f4f8-46ab-9464-c63ead502e31'	System	30 Jul 2020 22:55:11
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 22:55:11

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:54:52', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1ba0887c-f4f8-46ab-9464-c63ead502e31' User entered 'No (N)'	System	30 Jul 2020 22:55:11
	System	30 Jul 2020 22:55:11

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:54:54', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1ba0887c-f4f8-46ab-9464-c63ead502e31' User entered 'No (N)'	System	30 Jul 2020 22:55:11
	System	30 Jul 2020 22:55:11

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:54:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1ba0887c-f4f8-46ab-9464-c63ead502e31' User entered 'None (1)'	System	30 Jul 2020 22:55:11
	System	30 Jul 2020 22:55:11

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1ba0887c-f4f8-46ab-9464-c63ead502e31' User entered '30 Jul 2020 18:55'	System	30 Jul 2020 22:55:11
	System	30 Jul 2020 22:55:11



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 4'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:30', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b739164e-6368-4613-83e9-8beb9fb6c380' User entered 'None (1)'	System	24 Aug 2020 13:27:01
	System	24 Aug 2020 13:27:01

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:39', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b739164e-6368-4613-83e9-8beb9fb6c380' User entered 'No (N)'	System	24 Aug 2020 13:27:01
	System	24 Aug 2020 13:27:01

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b739164e-6368-4613-83e9-8beb9fb6c380' User entered 'No (N)'	System	24 Aug 2020 13:27:01
	System	24 Aug 2020 13:27:01

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:41', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b739164e-6368-4613-83e9-8beb9fb6c380' User entered 'None (1)'	System	24 Aug 2020 13:27:01
	System	24 Aug 2020 13:27:01

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b739164e-6368-4613-83e9-8beb9fb6c380' User entered '31 Jul 2020 16:11'	System	24 Aug 2020 13:27:01
	System	24 Aug 2020 13:27:01



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 5'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '83364dc2-f517-4bef-8105-f5db1a7082fb' User entered 'None (1)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:16', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '83364dc2-f517-4bef-8105-f5db1a7082fb' User entered 'No (N)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '83364dc2-f517-4bef-8105-f5db1a7082fb' User entered 'No (N)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '83364dc2-f517-4bef-8105-f5db1a7082fb' User entered 'None (1)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:22', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '83364dc2-f517-4bef-8105-f5db1a7082fb' User entered '01 Aug 2020 21:44'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 6'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:28:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7f0ee908-340a-418d-92bb-35c2b15fbe1d' User entered 'None (1)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:28:52', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7f0ee908-340a-418d-92bb-35c2b15fbe1d' User entered 'No (N)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:28:54', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7f0ee908-340a-418d-92bb-35c2b15fbe1d' User entered 'No (N)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:28:56', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7f0ee908-340a-418d-92bb-35c2b15fbe1d' User entered 'None (1)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:01', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7f0ee908-340a-418d-92bb-35c2b15fbe1d' User entered '02 Aug 2020 19:29'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 7'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:50:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '869a2a8d-a263-4ba1-b1b6-d21048927e68' User entered 'None (1)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:50:59', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '869a2a8d-a263-4ba1-b1b6-d21048927e68' User entered 'No (N)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:01', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '869a2a8d-a263-4ba1-b1b6-d21048927e68' User entered 'No (N)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '869a2a8d-a263-4ba1-b1b6-d21048927e68' User entered 'None (1)'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '869a2a8d-a263-4ba1-b1b6-d21048927e68' User entered '03 Aug 2020 13:51'	System	24 Aug 2020 13:27:07
	System	24 Aug 2020 13:27:07



US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:26', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered 'None (0)'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered 'None (0)'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:41', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered 'None (0)'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered 'None (0)'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:46', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered 'None (0)'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered 'None (0)'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:05:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered 'No (N)'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-28T10:06:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '14ac17db-29ff-46b3-a0e7-cc5b44bd8380' User entered '28 Jul 2020 10:06'	System	28 Jul 2020 14:06:06
	System	28 Jul 2020 14:06:06

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 10:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 12:30'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Jul 2020 13:25'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 13:49:48



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 2'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:23', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered 'None (0)'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:21', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered 'None (0)'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered 'None (0)'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:26', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered 'None (0)'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered 'None (0)'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:32', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered 'None (0)'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:35', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered 'No (N)'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-29T18:47:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '659fc765-43bf-4aed-abe5-e667b09d051a' User entered '29 Jul 2020 18:47'	System	29 Jul 2020 22:47:56
	System	29 Jul 2020 22:47:56

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 3'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:05', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2'	System	30 Jul 2020 22:56:04
User entered 'No interference with activity (1)'	System	30 Jul 2020 22:56:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2' User entered 'None (0)'	System	30 Jul 2020 22:56:04
	System	30 Jul 2020 22:56:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:10', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2' User entered 'None (0)'	System	30 Jul 2020 22:56:04
	System	30 Jul 2020 22:56:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:15', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2' User entered 'None (0)'	System	30 Jul 2020 22:56:04
	System	30 Jul 2020 22:56:04



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2'	System	30 Jul 2020 22:56:04
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	30 Jul 2020 22:56:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:22', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2'	System	30 Jul 2020 22:56:04
User entered 'None (0)'	System	30 Jul 2020 22:56:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:26', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2' User entered 'No (N)'	System	30 Jul 2020 22:56:04
	System	30 Jul 2020 22:56:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-30T18:55:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6c0f8a22-cffb-4e30-9559-a5604c002da2' User entered '30 Jul 2020 18:55'	System	30 Jul 2020 22:56:04
	System	30 Jul 2020 22:56:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 4'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:47', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:49', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:51', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:11:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:12:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered 'No (N)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-07-31T16:12:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8d4f8a09-25fc-4312-8264-703313598df9' User entered '31 Jul 2020 16:12'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 13:49:48



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 5'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:31', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:32', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:33', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:35', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:36', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered 'None (0)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered 'No (N)'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-01T21:44:40', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e00543dd-1a28-4cee-ac5d-2c72a1087f2a' User entered '01 Aug 2020 21:44'	System	24 Aug 2020 13:27:04
	System	24 Aug 2020 13:27:04

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 6'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered 'None (0)'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:06', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered 'None (0)'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered 'None (0)'	System	24 Aug 2020 13:27:07



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:10', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered 'None (0)'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:12', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered 'None (0)'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered 'None (0)'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:16', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered 'No (N)'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-02T19:29:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca98df40-d07d-4287-a49c-ed25cfebf27'	System	24 Aug 2020 13:27:07
User entered '02 Aug 2020 19:29'	System	24 Aug 2020 13:27:07

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 7'	System	28 Jul 2020 13:49:48



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered 'None (0)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:09', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered 'None (0)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:11', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered 'None (0)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:13', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered 'None (0)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered 'None (0)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:15', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered 'None (0)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered 'No (N)'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-03T13:51:21', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e64b56d1-d6c4-40f5-ad88-743fc77fcf57' User entered '03 Aug 2020 13:51'	System	24 Aug 2020 13:27:09
	System	24 Aug 2020 13:27:09



US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 13:49:48

US3182025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:25:28

US3182025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered '05 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:25:28

US3182025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:25:28

US3182025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 14:25:28
	(b) (4)	

US3182025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 14:25:20

US3182025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'I'	System	07 Aug 2020 14:25:20



US3182025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:53:13

US3182025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered '11 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:53:13

US3182025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:53:13

US3182025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:53:13
	(b) (4)	

US3182025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	24 Aug 2020 13:04:16

US3182025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User entered 'I'	System	24 Aug 2020 13:04:16

US3182025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:44:24

US3182025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered '18 Aug 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:44:24



US3182025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:44:24

US3182025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:44:24

US3182025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4)	
	Brooke Glivar (b) (4)	24 Aug 2020 13:04:44
	(b) (4)	

US3182025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User entered 'I'	System	24 Aug 2020 13:04:44

US3182025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	24 Aug 2020 13:04:59

US3182025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:31:11
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Aug 2020 13:04:59
User entered '24 Aug 2020'	Brooke Glivar (b) (4) (b) (4)	24 Aug 2020 13:04:59

US3182025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Clinic (Clinic)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	24 Aug 2020 13:04:59

US3182025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'VISIT2'	System	24 Aug 2020 13:04:59



US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '07:50'	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:55:13
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '24 Aug 2020 07:50'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '98.1' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:55:13
	(b) (4)	



US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '80'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'bpm'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '15'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'breaths/min'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '93'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '67'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	25 Aug 2020 14:55:13



US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '09:34'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '24 Aug 2020 09:34'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '98.7' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Oral (Oral)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:55:13
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:55:13
	(b) (4)	



US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '74'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'bpm'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'breaths/min'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '101'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '67'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:13

US3182025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	25 Aug 2020 14:55:13



US3182025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:55:59

US3182025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Aug 2020'	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:55:59
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:57:34

US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:57:34

US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Urine (URINE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:57:34

US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Negative (NEGATIVE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:57:34

US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:57:34
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:57:34
	(b) (4)	



US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:57:34
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:35:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered empty.	System	25 Aug 2020 14:57:34

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
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	24 Aug 2020 13:06:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	24 Aug 2020 13:06:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	24 Aug 2020 13:06:06
	Brooke Glivar (b) (4)	24 Aug 2020 13:06:06
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Brooke Glivar (b) (4)	24 Aug 2020 13:06:06
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4) Brooke Glivar (b) (4) (b) (4)	24 Aug 2020 13:06:06

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 13:06:16
User entered empty.	System	24 Aug 2020 13:06:06

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Aug 2020'	(b) (4) Brooke Glivar (b) (4) (b) (4)	24 Aug 2020 13:06:06

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '08:53'	(b) (4)	
	Brooke Glivar (b) (4)	24 Aug 2020 13:06:06
	(b) (4)	



US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '24 Aug 2020 08:53'	System	24 Aug 2020 13:06:06

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	24 Aug 2020 13:06:06

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'ONCE'	System	24 Aug 2020 13:06:16
User entered empty.	System	24 Aug 2020 13:06:06

US3182025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 13:06:16
User entered empty.	System	24 Aug 2020 13:06:06

US3182025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:57:47

US3182025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:57:47

US3182025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '08:23'	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:57:47
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '24 Aug 2020 08:23'	System	25 Aug 2020 14:57:47



US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:56:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:56:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:56:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '08:15'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:56:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '24 Aug 2020 08:15'	System	25 Aug 2020 14:56:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:56:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Aug 2020 14:56:23
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Aug 2020 14:56:23



US3182025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered empty.	System	25 Aug 2020 14:56:23

US3182025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Aug 2020 14:58:00
	(b) (4)	

US3182025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'I'	System	25 Aug 2020 14:58:00

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:28:48', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '587179a7-95aa-48e8-b162-a4d7b544213f' User entered 'Yes (Y)'	System	24 Aug 2020 13:29:13
	System	24 Aug 2020 13:29:13

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:07', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '587179a7-95aa-48e8-b162-a4d7b544213f' User entered '98.7'	System	24 Aug 2020 13:29:13
	System	24 Aug 2020 13:29:13

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:28:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '587179a7-95aa-48e8-b162-a4d7b544213f' User entered 'No (N)'	System	24 Aug 2020 13:29:13
	System	24 Aug 2020 13:29:13

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:10', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '587179a7-95aa-48e8-b162-a4d7b544213f' User entered '24 Aug 2020 09:29'	System	24 Aug 2020 13:29:13
	System	24 Aug 2020 13:29:13



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 09:13'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 11:43'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:09:43', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd295fdbd-0d0e-4be4-ae61-c6d755cbe6e9' User entered 'Yes (Y)'	System	24 Aug 2020 20:10:33
	System	24 Aug 2020 20:10:33

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:10:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd295fdbd-0d0e-4be4-ae61-c6d755cbe6e9' User entered '98.8'	System	24 Aug 2020 20:10:33
	System	24 Aug 2020 20:10:33

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:10:22', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd295fdbd-0d0e-4be4-ae61-c6d755cbe6e9'	System	24 Aug 2020 20:10:33
User entered 'Yes (Y)'	System	24 Aug 2020 20:10:33

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4)	18 Oct 2020 11:43:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Cassie Uminski (b) (4)	05 Oct 2020 14:57:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:10:28', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd295fdbd-0d0e-4be4-ae61-c6d755cbe6e9'	(b) (4)	
User entered '1'	System	24 Aug 2020 20:10:33
	System	24 Aug 2020 20:10:33
	System	24 Aug 2020 20:10:33

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:10:28', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd295fdbd-0d0e-4be4-ae61-c6d755cbe6e9' User entered '0'	System	24 Aug 2020 20:10:33
	System	24 Aug 2020 20:10:33



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:10:30', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd295fdbd-0d0e-4be4-ae61-c6d755cbe6e9' User entered '24 Aug 2020 16:10'	System	24 Aug 2020 20:10:33
	System	24 Aug 2020 20:10:33

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 12:38'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 2'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '791a1717-3960-4ba7-96f5-07a3aa187a2f' User entered 'Yes (Y)'	System	25 Aug 2020 16:00:48
	System	25 Aug 2020 16:00:48

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:32', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '791a1717-3960-4ba7-96f5-07a3aa187a2f' User entered '102.2'	System	25 Aug 2020 16:00:48
	System	25 Aug 2020 16:00:48

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:34', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '791a1717-3960-4ba7-96f5-07a3aa187a2f' User entered 'Yes (Y)'	System	25 Aug 2020 16:00:48
	System	25 Aug 2020 16:00:48

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4)	18 Oct 2020 11:43:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '791a1717-3960-4ba7-96f5-07a3aa187a2f' User entered '1'	Cassie Uminski (b) (4)	05 Oct 2020 14:58:01
	(b) (4)	
	System	25 Aug 2020 16:00:48
	System	25 Aug 2020 16:00:48
	System	25 Aug 2020 16:00:48



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '791a1717-3960-4ba7-96f5-07a3aa187a2f' User entered '0'	System	25 Aug 2020 16:00:48
	System	25 Aug 2020 16:00:48

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:41', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '791a1717-3960-4ba7-96f5-07a3aa187a2f' User entered '25 Aug 2020 12:00'	System	25 Aug 2020 16:00:48
	System	25 Aug 2020 16:00:48

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 3'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:36', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f27da657-5a9f-4833-8d05-354aa4744be2'	System	26 Aug 2020 17:58:02
User entered 'Yes (Y)'	System	26 Aug 2020 17:58:02

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:43', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f27da657-5a9f-4833-8d05-354aa4744be2' User entered '99.1'	System	26 Aug 2020 17:58:02
	System	26 Aug 2020 17:58:02

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f27da657-5a9f-4833-8d05-354aa4744be2'	System	26 Aug 2020 17:58:02
User entered 'No (N)'	System	26 Aug 2020 17:58:02



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'f27da657-5a9f-4833-8d05-354aa4744be2' User entered '26 Aug 2020 13:57'	System	26 Aug 2020 17:58:02
	System	26 Aug 2020 17:58:02

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 4'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'df53243a-c3b5-4f38-a949-a5aa2f5f25be' User entered 'Yes (Y)'	System	27 Aug 2020 22:36:04
	System	27 Aug 2020 22:36:04

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'df53243a-c3b5-4f38-a949-a5aa2f5f25be' User entered '98.3'	System	27 Aug 2020 22:36:04
	System	27 Aug 2020 22:36:04

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:36:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'df53243a-c3b5-4f38-a949-a5aa2f5f25be' User entered 'No (N)'	System	27 Aug 2020 22:36:04
	System	27 Aug 2020 22:36:04

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:36:01', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'df53243a-c3b5-4f38-a949-a5aa2f5f25be' User entered '27 Aug 2020 18:36'	System	27 Aug 2020 22:36:04
	System	27 Aug 2020 22:36:04



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 5'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b4e6f491-23a1-42a9-88a6-6333e0cb8448' User entered 'Yes (Y)'	System	28 Aug 2020 22:08:21
	System	28 Aug 2020 22:08:21

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:08:15', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b4e6f491-23a1-42a9-88a6-6333e0cb8448' User entered '98.0'	System	28 Aug 2020 22:08:21
	System	28 Aug 2020 22:08:21

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:08:17', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b4e6f491-23a1-42a9-88a6-6333e0cb8448'	System	28 Aug 2020 22:08:21
User entered 'No (N)'	System	28 Aug 2020 22:08:21

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:08:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b4e6f491-23a1-42a9-88a6-6333e0cb8448' User entered '28 Aug 2020 18:08'	System	28 Aug 2020 22:08:21
	System	28 Aug 2020 22:08:21

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 6'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:43', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'bb356b89-1484-4fa1-83a3-aa958689c4c7'	System	30 Aug 2020 01:24:04
User entered 'Yes (Y)'	System	30 Aug 2020 01:24:04

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'bb356b89-1484-4fa1-83a3-aa958689c4c7' User entered '97.9'	System	30 Aug 2020 01:24:04
	System	30 Aug 2020 01:24:04

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:56', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'bb356b89-1484-4fa1-83a3-aa958689c4c7'	System	30 Aug 2020 01:24:04
User entered 'No (N)'	System	30 Aug 2020 01:24:04

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:24:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'bb356b89-1484-4fa1-83a3-aa958689c4c7'	System	30 Aug 2020 01:24:04
User entered '29 Aug 2020 21:24'	System	30 Aug 2020 01:24:04

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 7'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:22', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b2299fa3-7654-4af8-8427-247d5b18d0ca' User entered 'Yes (Y)'	System	30 Aug 2020 16:08:47
	System	30 Aug 2020 16:08:47

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:37', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b2299fa3-7654-4af8-8427-247d5b18d0ca' User entered '98.0'	System	30 Aug 2020 16:08:47
	System	30 Aug 2020 16:08:47

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:43', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b2299fa3-7654-4af8-8427-247d5b18d0ca' User entered 'No (N)'	System	30 Aug 2020 16:08:47
	System	30 Aug 2020 16:08:47

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:46', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b2299fa3-7654-4af8-8427-247d5b18d0ca' User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:47
	System	30 Aug 2020 16:08:47

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:31:37', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca950847-ded7-4e07-bb56-a09228bb1577'	System	24 Aug 2020 13:32:33
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 13:32:33

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:32:19', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca950847-ded7-4e07-bb56-a09228bb1577'	System	24 Aug 2020 13:32:33
User entered 'No (N)'	System	24 Aug 2020 13:32:33

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:32:23', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca950847-ded7-4e07-bb56-a09228bb1577'	System	24 Aug 2020 13:32:33
User entered 'No (N)'	System	24 Aug 2020 13:32:33

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:32:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca950847-ded7-4e07-bb56-a09228bb1577'	System	24 Aug 2020 13:32:33
User entered 'None (1)'	System	24 Aug 2020 13:32:33

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:32:30', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ca950847-ded7-4e07-bb56-a09228bb1577'	System	24 Aug 2020 13:32:33
User entered '24 Aug 2020 09:32'	System	24 Aug 2020 13:32:33

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 09:13'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 11:43'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1-2, Pain at Injection Site and Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).		23 Oct 2020 12:24:34
Query 'Per DM CLR: Per Diary Dose 2 Day 1-2, Pain at Injection Site and Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'corrected' (Site from DM).	Amy Maroun (b) (4) (b) (4)	16 Oct 2020 13:16:23
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1-2, Pain at Injection Site and Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:40:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:11:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10972dcc-4239-4e44-bef9-74a15e1b9798'	System	24 Aug 2020 20:11:46
User entered 'Any use of prescription pain reliever or prevents daily activity (4)'	System	24 Aug 2020 20:11:46

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:11:05', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10972dcc-4239-4e44-bef9-74a15e1b9798' User entered 'No (N)'	System	24 Aug 2020 20:11:46
	System	24 Aug 2020 20:11:46

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:11:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10972dcc-4239-4e44-bef9-74a15e1b9798'	System	24 Aug 2020 20:11:46
User entered 'No (N)'	System	24 Aug 2020 20:11:46

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:11:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10972dcc-4239-4e44-bef9-74a15e1b9798'	System	24 Aug 2020 20:11:46
User entered 'None (1)'	System	24 Aug 2020 20:11:46

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:11:28', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10972dcc-4239-4e44-bef9-74a15e1b9798'	System	24 Aug 2020 20:11:46
User entered '24 Aug 2020 16:11'	System	24 Aug 2020 20:11:46

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 12:38'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 2'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '857ef481-c497-4117-b734-32fd3b08e66a'	System	25 Aug 2020 16:01:12
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		25 Aug 2020 16:01:12

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '857ef481-c497-4117-b734-32fd3b08e66a' User entered 'No (N)'	System	25 Aug 2020 16:01:12
	System	25 Aug 2020 16:01:12

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '857ef481-c497-4117-b734-32fd3b08e66a' User entered 'No (N)'	System	25 Aug 2020 16:01:12
	System	25 Aug 2020 16:01:12

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '857ef481-c497-4117-b734-32fd3b08e66a' User entered 'None (1)'	System	25 Aug 2020 16:01:12
	System	25 Aug 2020 16:01:12

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:00:59', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '857ef481-c497-4117-b734-32fd3b08e66a'	System	25 Aug 2020 16:01:12
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 16:01:12

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 3'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:56:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10f82c49-a4ee-4640-a48a-4f3f7e114159'	System	26 Aug 2020 17:57:04
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 17:57:04

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:56:21', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10f82c49-a4ee-4640-a48a-4f3f7e114159' User entered 'No (N)'	System	26 Aug 2020 17:57:04
	System	26 Aug 2020 17:57:04

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:56:49', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10f82c49-a4ee-4640-a48a-4f3f7e114159' User entered 'No (N)'	System	26 Aug 2020 17:57:04
	System	26 Aug 2020 17:57:04

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:56:52', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10f82c49-a4ee-4640-a48a-4f3f7e114159' User entered 'None (1)'	System	26 Aug 2020 17:57:04
	System	26 Aug 2020 17:57:04

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:56:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '10f82c49-a4ee-4640-a48a-4f3f7e114159' User entered '26 Aug 2020 13:56'	System	26 Aug 2020 17:57:04
	System	26 Aug 2020 17:57:04

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 4'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:12', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84b5a1e9-a65b-4860-8115-64a34026e4dd'	System	27 Aug 2020 22:35:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 22:35:25

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:15', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84b5a1e9-a65b-4860-8115-64a34026e4dd' User entered 'No (N)'	System	27 Aug 2020 22:35:25
	System	27 Aug 2020 22:35:25

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:17', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84b5a1e9-a65b-4860-8115-64a34026e4dd'	System	27 Aug 2020 22:35:25
User entered 'No (N)'	System	27 Aug 2020 22:35:25

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84b5a1e9-a65b-4860-8115-64a34026e4dd' User entered 'None (1)'	System	27 Aug 2020 22:35:25
	System	27 Aug 2020 22:35:25

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:23', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84b5a1e9-a65b-4860-8115-64a34026e4dd' User entered '27 Aug 2020 18:35'	System	27 Aug 2020 22:35:25
	System	27 Aug 2020 22:35:25

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 5'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9f96c896-97b4-44f5-92cc-1c1f40ba11ac'	System	28 Aug 2020 22:07:47
User entered 'None (1)'	System	28 Aug 2020 22:07:47

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:35', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9f96c896-97b4-44f5-92cc-1c1f40ba11ac' User entered 'No (N)'	System	28 Aug 2020 22:07:47
	System	28 Aug 2020 22:07:47

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9f96c896-97b4-44f5-92cc-1c1f40ba11ac' User entered 'No (N)'	System	28 Aug 2020 22:07:47
	System	28 Aug 2020 22:07:47

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:39', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9f96c896-97b4-44f5-92cc-1c1f40ba11ac'	System	28 Aug 2020 22:07:47
User entered 'None (1)'	System	28 Aug 2020 22:07:47

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:42', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9f96c896-97b4-44f5-92cc-1c1f40ba11ac' User entered '28 Aug 2020 18:07'	System	28 Aug 2020 22:07:47
	System	28 Aug 2020 22:07:47

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 6'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:22', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6468393d-4e8d-4d9e-9491-c4d0d964e0c8' User entered 'None (1)'	System	30 Aug 2020 01:23:42
	System	30 Aug 2020 01:23:42

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:25', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6468393d-4e8d-4d9e-9491-c4d0d964e0c8' User entered 'No (N)'	System	30 Aug 2020 01:23:42
	System	30 Aug 2020 01:23:42

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6468393d-4e8d-4d9e-9491-c4d0d964e0c8' User entered 'No (N)'	System	30 Aug 2020 01:23:42
	System	30 Aug 2020 01:23:42

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6468393d-4e8d-4d9e-9491-c4d0d964e0c8' User entered 'None (1)'	System	30 Aug 2020 01:23:42
	System	30 Aug 2020 01:23:42

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6468393d-4e8d-4d9e-9491-c4d0d964e0c8' User entered '29 Aug 2020 21:23'	System	30 Aug 2020 01:23:42
	System	30 Aug 2020 01:23:42

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 7'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:05', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c6491a53-2c0c-4261-bbef-f4fc08cd5576'	System	30 Aug 2020 16:08:19
User entered 'None (1)'	System	30 Aug 2020 16:08:19

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c6491a53-2c0c-4261-bbef-f4fc08cd5576' User entered 'No (N)'	System	30 Aug 2020 16:08:19
	System	30 Aug 2020 16:08:19

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:09', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c6491a53-2c0c-4261-bbef-f4fc08cd5576'	System	30 Aug 2020 16:08:19
User entered 'No (N)'	System	30 Aug 2020 16:08:19

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:11', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c6491a53-2c0c-4261-bbef-f4fc08cd5576' User entered 'None (1)'	System	30 Aug 2020 16:08:19
	System	30 Aug 2020 16:08:19

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:16', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'c6491a53-2c0c-4261-bbef-f4fc08cd5576' User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:19
	System	30 Aug 2020 16:08:19

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:40', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408'	System	24 Aug 2020 13:30:03
User entered 'No interference with activity (1)'	System	24 Aug 2020 13:30:03

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:43', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408'	System	24 Aug 2020 13:30:03
User entered 'No interference with activity (1)'	System	24 Aug 2020 13:30:03

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:45', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408' User entered 'None (0)'	System	24 Aug 2020 13:30:03
	System	24 Aug 2020 13:30:03

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:48', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408' User entered 'None (0)'	System	24 Aug 2020 13:30:03
	System	24 Aug 2020 13:30:03

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408' User entered 'None (0)'	System	24 Aug 2020 13:30:03
	System	24 Aug 2020 13:30:03

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:54', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408'	System	24 Aug 2020 13:30:03
User entered 'No interference with activity (1)'	System	24 Aug 2020 13:30:03

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:56', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408'	System	24 Aug 2020 13:30:03
User entered 'No (N)'	System	24 Aug 2020 13:30:03

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T09:29:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b825284-8f23-4efb-bd2d-3b7600447408' User entered '24 Aug 2020 09:29'	System	24 Aug 2020 13:30:03
	System	24 Aug 2020 13:30:03



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 09:13'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 11:43'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:07:48', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09'	System	24 Aug 2020 20:08:13
User entered 'No interference with activity (1)'	System	24 Aug 2020 20:08:13

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:07:52', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09' User entered 'Some interference with activity (2)'	System	24 Aug 2020 20:08:13
	System	24 Aug 2020 20:08:13

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:07:54', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09' User entered 'None (0)'	System	24 Aug 2020 20:08:13
	System	24 Aug 2020 20:08:13

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:07:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09' User entered 'None (0)'	System	24 Aug 2020 20:08:13
	System	24 Aug 2020 20:08:13

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:08:01', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09' User entered 'None (0)'	System	24 Aug 2020 20:08:13
	System	24 Aug 2020 20:08:13



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:08:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09' User entered 'No interference with activity (1)'	System	24 Aug 2020 20:08:13
	System	24 Aug 2020 20:08:13

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:08:07', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09' User entered 'No (N)'	System	24 Aug 2020 20:08:13
	System	24 Aug 2020 20:08:13

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-24T16:08:09', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0e621cc1-54a7-4214-a089-214911878c09' User entered '24 Aug 2020 16:08'	System	24 Aug 2020 20:08:13
	System	24 Aug 2020 20:08:13

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '24 Aug 2020 12:38'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 2'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7'	System	25 Aug 2020 16:02:16
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		25 Aug 2020 16:02:16

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7'	System	25 Aug 2020 16:02:16
User entered 'Significant; prevents daily activity (3)'	System	25 Aug 2020 16:02:16



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7'	System	25 Aug 2020 16:02:16
User entered 'Some interference with activity (2)'	System	25 Aug 2020 16:02:16

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:21', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7'	System	25 Aug 2020 16:02:16
User entered 'Some interference with activity (2)'	System	25 Aug 2020 16:02:16

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7'	System	25 Aug 2020 16:02:16
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	25 Aug 2020 16:02:16

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:36', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7'	System	25 Aug 2020 16:02:16
User entered 'Some interference with activity not requiring medical attention (2)'	System	25 Aug 2020 16:02:16

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:42', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7'	System	25 Aug 2020 16:02:16
User entered 'Yes (Y)'	System	25 Aug 2020 16:02:16

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-25T12:01:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2ae6f942-d902-4de7-906d-3f5e7ea59ce7' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:02:16
	System	25 Aug 2020 16:02:16

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 3'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:05', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2'	System	26 Aug 2020 17:57:28
User entered 'No interference with activity (1)'	System	26 Aug 2020 17:57:28

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:09', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2'	System	26 Aug 2020 17:57:28
User entered 'Some interference with activity (2)'	System	26 Aug 2020 17:57:28

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2' User entered 'None (0)'	System	26 Aug 2020 17:57:28
	System	26 Aug 2020 17:57:28

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:16', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2' User entered 'None (0)'	System	26 Aug 2020 17:57:28
	System	26 Aug 2020 17:57:28

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2' User entered 'None (0)'	System	26 Aug 2020 17:57:28
	System	26 Aug 2020 17:57:28

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2' User entered 'None (0)'	System	26 Aug 2020 17:57:28
	System	26 Aug 2020 17:57:28

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:24', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2'	System	26 Aug 2020 17:57:28
User entered 'No (N)'	System	26 Aug 2020 17:57:28



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-26T13:57:26', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0bfbf132-6035-4026-a7c5-25814c7e67a2'	System	26 Aug 2020 17:57:28
User entered '26 Aug 2020 13:57'	System	26 Aug 2020 17:57:28

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 4'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:34:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered 'None (0)'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:34:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered 'None (0)'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:34:59', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered 'None (0)'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:01', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered 'None (0)'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered 'None (0)'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered 'None (0)'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:05', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered 'No (N)'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12

**US3182025**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:35:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-27T18:35:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '5abe362d-72c9-4133-93d0-3ae881c9e8ee' User entered '27 Aug 2020 18:35'	System	27 Aug 2020 22:35:12
	System	27 Aug 2020 22:35:12

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 5'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4'	System	28 Aug 2020 22:07:26
User entered 'No interference with activity (1)'	System	28 Aug 2020 22:07:26



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:11', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4' User entered 'None (0)'	System	28 Aug 2020 22:07:26
	System	28 Aug 2020 22:07:26

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:13', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4' User entered 'None (0)'	System	28 Aug 2020 22:07:26
	System	28 Aug 2020 22:07:26

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4' User entered 'None (0)'	System	28 Aug 2020 22:07:26
	System	28 Aug 2020 22:07:26

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:16', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4' User entered 'None (0)'	System	28 Aug 2020 22:07:26
	System	28 Aug 2020 22:07:26

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:19', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4' User entered 'None (0)'	System	28 Aug 2020 22:07:26
	System	28 Aug 2020 22:07:26

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4' User entered 'No (N)'	System	28 Aug 2020 22:07:26
	System	28 Aug 2020 22:07:26

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-28T18:07:24', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '80146b5b-e019-4820-ba47-9a94fa0858d4' User entered '28 Aug 2020 18:07'	System	28 Aug 2020 22:07:26
	System	28 Aug 2020 22:07:26

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:06:06



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 6'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:22:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949'	System	30 Aug 2020 01:23:17
User entered 'No interference with activity (1)'	System	30 Aug 2020 01:23:17

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949' User entered 'None (0)'	System	30 Aug 2020 01:23:17
	System	30 Aug 2020 01:23:17

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:05', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949'	System	30 Aug 2020 01:23:17
User entered 'No interference with activity (1)'	System	30 Aug 2020 01:23:17

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:07', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949' User entered 'None (0)'	System	30 Aug 2020 01:23:17
	System	30 Aug 2020 01:23:17

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:09', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949' User entered 'None (0)'	System	30 Aug 2020 01:23:17
	System	30 Aug 2020 01:23:17

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:10', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949' User entered 'None (0)'	System	30 Aug 2020 01:23:17
	System	30 Aug 2020 01:23:17



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:12', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949' User entered 'No (N)'	System	30 Aug 2020 01:23:17
	System	30 Aug 2020 01:23:17

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-29T21:23:15', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'dde89809-45b4-4232-a5f7-252e5939b949'	System	30 Aug 2020 01:23:17
User entered '29 Aug 2020 21:23'	System	30 Aug 2020 01:23:17

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	24 Aug 2020 13:06:06
User entered 'Day 7'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:07:49', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5' User entered 'None (0)'	System	30 Aug 2020 16:08:04
	System	30 Aug 2020 16:08:04

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:07:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5'	System	30 Aug 2020 16:08:04
User entered 'None (0)'	System	30 Aug 2020 16:08:04

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:07:52', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5' User entered 'None (0)'	System	30 Aug 2020 16:08:04
	System	30 Aug 2020 16:08:04



US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:07:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5' User entered 'None (0)'	System	30 Aug 2020 16:08:04
	System	30 Aug 2020 16:08:04

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:07:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5' User entered 'None (0)'	System	30 Aug 2020 16:08:04
	System	30 Aug 2020 16:08:04

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:07:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5'	System	30 Aug 2020 16:08:04
User entered 'None (0)'	System	30 Aug 2020 16:08:04

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:07:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5'	System	30 Aug 2020 16:08:04
User entered 'No (N)'	System	30 Aug 2020 16:08:04

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-08-30T12:08:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'fa58fc05-3fa8-43d5-80f0-c1724e4fc3c5' User entered '30 Aug 2020 12:08'	System	30 Aug 2020 16:08:04
	System	30 Aug 2020 16:08:04

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:06:06

US3182025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:06:06

US3182025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	01 Sep 2020 17:45:38



US3182025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered '1 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	01 Sep 2020 17:45:38

US3182025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	01 Sep 2020 17:45:38

US3182025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	01 Sep 2020 17:45:38

US3182025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:56:15
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	01 Sep 2020 17:45:43

US3182025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User entered 'I'	System	01 Sep 2020 17:45:43

US3182025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	08 Sep 2020 16:20:57

US3182025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '8 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	08 Sep 2020 16:20:57

US3182025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	08 Sep 2020 16:20:57



US3182025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	08 Sep 2020 16:20:57

US3182025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	08 Sep 2020 16:20:50

US3182025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User entered 'I'	System	08 Sep 2020 16:20:50

US3182025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Nov 2020 19:01:37

US3182025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '15 Sep 2020'	(b) (4)	
	Cassie Uminski (b) (4)	13 Nov 2020 19:01:37
	(b) (4)	

US3182025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	13 Nov 2020 19:01:37

US3182025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	13 Nov 2020 19:01:37
	(b) (4)	

US3182025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:18:17
	(b) (4)	



US3182025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:19
User entered 'I'	System	25 Sep 2020 12:18:17

US3182025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:19:43

US3182025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Sep 2020'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:19:43
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:19:43

US3182025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'VISIT3'	System	25 Sep 2020 12:19:43

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Sep 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '15:19'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:19:59
	(b) (4)	



US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '24 Sep 2020 15:19'	System	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '98.4' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Oral (Oral)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:19:59
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:19:59
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '73'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:19:59
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'bpm'	System	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '14'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:19:59
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'breaths/min'	System	25 Sep 2020 12:19:59



US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '113'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '78'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'mmHg'	System	25 Sep 2020 12:19:59

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30

US3182025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30

US3182025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:20:09
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:20:09
	(b) (4)	



US3182025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Oct 2020 18:41:27

US3182025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '24 Sep 2020'	(b) (4)	
	Cassie Uminski (b) (4)	02 Oct 2020 18:41:27
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered '15:28'	(b) (4)	
	Cassie Uminski (b) (4)	02 Oct 2020 18:41:27
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '24 Sep 2020 15:28'	System	02 Oct 2020 18:41:27

US3182025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	15 Feb 2021 18:56:17
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Sep 2020 12:20:36
	(b) (4)	

US3182025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered '1'	System	25 Sep 2020 12:20:36

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 64'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-09-29T08:02:26', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '94b70258-3bfc-48ff-a08c-7968f3035214'	System	29 Sep 2020 12:02:37
User entered 'No (N)'	System	29 Sep 2020 12:02:37



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-09-29T08:02:29', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '94b70258-3bfc-48ff-a08c-7968f3035214'	System	29 Sep 2020 12:02:37
User entered 'No (N)'	System	29 Sep 2020 12:02:37

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-09-29T08:02:32', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '94b70258-3bfc-48ff-a08c-7968f3035214' User entered '29 Sep 2020 08:02:32'	System	29 Sep 2020 12:02:37
	System	29 Sep 2020 12:02:37

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '27 Sep 2020 00:01'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '01 Oct 2020 23:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 71'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-04T23:13:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0841e05c-1155-4d82-afca-81a9cc669120' User entered 'No (N)'	System	05 Oct 2020 03:13:34
	System	05 Oct 2020 03:13:34

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-04T23:13:31', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0841e05c-1155-4d82-afca-81a9cc669120'	System	05 Oct 2020 03:13:34
User entered 'No (N)'	System	05 Oct 2020 03:13:34

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-04T23:13:33', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0841e05c-1155-4d82-afca-81a9cc669120' User entered '04 Oct 2020 23:13:33'	System	05 Oct 2020 03:13:34
	System	05 Oct 2020 03:13:34



**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '04 Oct 2020 00:01'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '08 Oct 2020 23:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 78'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-12T14:56:43', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8cbd7cc3-aff5-4221-b6e5-5812f5f05f73'	System	12 Oct 2020 18:56:51
User entered 'No (N)'	System	12 Oct 2020 18:56:51

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-12T14:56:45', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8cbd7cc3-aff5-4221-b6e5-5812f5f05f73'	System	12 Oct 2020 18:56:51
User entered 'No (N)'	System	12 Oct 2020 18:56:51

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-12T14:56:47', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '8cbd7cc3-aff5-4221-b6e5-5812f5f05f73' User entered '12 Oct 2020 14:56:47'	System	12 Oct 2020 18:56:51
	System	12 Oct 2020 18:56:51

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '11 Oct 2020 00:01'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '15 Oct 2020 23:59'	System	28 Jul 2020 13:49:48



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 92'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-26T08:55:24', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '473a5842-5389-4d51-96ab-292ba0690b6c'	System	26 Oct 2020 12:55:37
User entered 'No (N)'	System	26 Oct 2020 12:55:37

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-26T08:55:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '473a5842-5389-4d51-96ab-292ba0690b6c'	System	26 Oct 2020 12:55:37
User entered 'No (N)'	System	26 Oct 2020 12:55:37

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-10-26T08:55:30', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '473a5842-5389-4d51-96ab-292ba0690b6c' User entered '26 Oct 2020 08:55:30'	System	26 Oct 2020 12:55:37
	System	26 Oct 2020 12:55:37

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '25 Oct 2020 00:01'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '29 Oct 2020 23:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 99'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-04T16:42:17', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '449c73b6-4cb3-4d18-a621-9f64e4707e37'	System	04 Nov 2020 21:42:43
User entered 'No (N)'	System	04 Nov 2020 21:42:43



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-04T16:42:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '449c73b6-4cb3-4d18-a621-9f64e4707e37'	System	04 Nov 2020 21:42:43
User entered 'Yes (Y)'	System	04 Nov 2020 21:42:43

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-04T16:42:28', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '449c73b6-4cb3-4d18-a621-9f64e4707e37'	System	04 Nov 2020 21:42:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 21:42:43

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-04T16:42:31', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '449c73b6-4cb3-4d18-a621-9f64e4707e37' User entered '04 Nov 2020 16:42:31'	System	04 Nov 2020 21:42:43
	System	04 Nov 2020 21:42:43

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '01 Nov 2020 00:01'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '05 Nov 2020 23:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 106'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:30', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954'	System	08 Nov 2020 05:02:12
User entered 'Yes (Y)'	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:34', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954'	System	08 Nov 2020 05:02:12
User entered 'No (N)'	System	08 Nov 2020 05:02:12



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:39', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954'	System	08 Nov 2020 05:02:12
User entered 'Yes (Y)'	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '0'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954'	System	08 Nov 2020 05:02:12
User entered '1'	System	08 Nov 2020 05:02:12

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:47', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954'	System	08 Nov 2020 05:02:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:51', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954'	System	08 Nov 2020 05:02:12
User entered 'No (N)'	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-08T00:01:56', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'ff1d20aa-a02c-4b85-83b0-24981c2ee954' User entered '08 Nov 2020 00:01:56'	System	08 Nov 2020 05:02:12
	System	08 Nov 2020 05:02:12

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '08 Nov 2020 00:01'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '12 Nov 2020 23:59'	System	28 Jul 2020 13:49:48

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered 'Day 113'	System	28 Jul 2020 13:49:48



US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-15T15:01:17', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51675fc1-9cca-47e2-b5f1-cbc894530ee5'	System	15 Nov 2020 20:01:26
User entered 'No (N)'	System	15 Nov 2020 20:01:26

US3182025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-15T15:01:21', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51675fc1-9cca-47e2-b5f1-cbc894530ee5'	System	15 Nov 2020 20:01:26
User entered 'No (N)'	System	15 Nov 2020 20:01:26

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-15T15:01:24', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '51675fc1-9cca-47e2-b5f1-cbc894530ee5' User entered '15 Nov 2020 15:01:24'	System	15 Nov 2020 20:01:26
	System	15 Nov 2020 20:01:26

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '15 Nov 2020 00:01'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:49:33
Data entry locked.	System	28 Jul 2020 13:49:48
User entered '19 Nov 2020 23:59'	System	28 Jul 2020 13:49:48

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-19T09:17:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '45491692-df5a-458d-a9f1-db81c7efe1b7'	System	19 Nov 2020 14:17:18
User entered 'No (N)'	System	19 Nov 2020 14:17:18

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-19T09:17:11', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '45491692-df5a-458d-a9f1-db81c7efe1b7'	System	19 Nov 2020 14:17:18
User entered 'No (N)'	System	19 Nov 2020 14:17:18



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-19T09:17:13', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '45491692-df5a-458d-a9f1-db81c7efe1b7' User entered '19 Nov 2020 09:17:13'	System	19 Nov 2020 14:17:18
	System	19 Nov 2020 14:17:18

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-27T05:42:31', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2806829a-793e-492d-b58b-b72da8d67834' User entered 'No (N)'	System	27 Nov 2020 10:42:41
	System	27 Nov 2020 10:42:41

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-27T05:42:33', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2806829a-793e-492d-b58b-b72da8d67834' User entered 'No (N)'	System	27 Nov 2020 10:42:41
	System	27 Nov 2020 10:42:41

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-11-27T05:42:37', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '2806829a-793e-492d-b58b-b72da8d67834' User entered '27 Nov 2020 05:42:37'	System	27 Nov 2020 10:42:41
	System	27 Nov 2020 10:42:41

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-03T13:06:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7bebc288-c84c-4e10-a3b1-63d98040d960' User entered 'No (N)'	System	03 Dec 2020 18:07:12
	System	03 Dec 2020 18:07:12

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-03T13:06:56', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7bebc288-c84c-4e10-a3b1-63d98040d960' User entered 'Yes (Y)'	System	03 Dec 2020 18:07:12
	System	03 Dec 2020 18:07:12

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Please 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-03T13:06:59', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7bebc288-c84c-4e10-a3b1-63d98040d960'	System	03 Dec 2020 18:07:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 18:07:12

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-03T13:07:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7bebc288-c84c-4e10-a3b1-63d98040d960' User entered '03 Dec 2020 13:07:02'	System	03 Dec 2020 18:07:12
	System	03 Dec 2020 18:07:12

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-10T12:33:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '636265e0-a7dc-4660-b2a9-60ba4708d4a3' User entered 'No (N)'	System	10 Dec 2020 17:34:02
	System	10 Dec 2020 17:34:02

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-10T12:33:54', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '636265e0-a7dc-4660-b2a9-60ba4708d4a3' User entered 'No (N)'	System	10 Dec 2020 17:34:02
	System	10 Dec 2020 17:34:02

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-10T12:33:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '636265e0-a7dc-4660-b2a9-60ba4708d4a3' User entered '10 Dec 2020 12:33:57'	System	10 Dec 2020 17:34:02

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-17T22:00:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '34761711-4f80-42ef-b58e-043ee3acb1f3' User entered 'No (N)'	System	18 Dec 2020 03:00:51
	System	18 Dec 2020 03:00:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-17T22:00:47', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '34761711-4f80-42ef-b58e-043ee3acb1f3'	System	18 Dec 2020 03:00:51
User entered 'No (N)'	System	18 Dec 2020 03:00:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-17T22:00:50', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '34761711-4f80-42ef-b58e-043ee3acb1f3' User entered '17 Dec 2020 22:00:50'	System	18 Dec 2020 03:00:51
	System	18 Dec 2020 03:00:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-27T09:39:40', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd56c27ae-cbd0-4d65-89d2-515ed99fc57f' User entered 'Yes (Y)'	System	27 Dec 2020 14:40:10
	System	27 Dec 2020 14:40:10

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-27T09:39:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd56c27ae-cbd0-4d65-89d2-515ed99fc57f' User entered 'No (N)'	System	27 Dec 2020 14:40:10
	System	27 Dec 2020 14:40:10

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-27T09:39:48', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd56c27ae-cbd0-4d65-89d2-515ed99fc57f' User entered 'No (N)'	System	27 Dec 2020 14:40:10
	System	27 Dec 2020 14:40:10



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-27T09:39:52', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd56c27ae-cbd0-4d65-89d2-515ed99fc57f'	System	27 Dec 2020 14:40:10
User entered 'Yes (Y)'	System	27 Dec 2020 14:40:10

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Please 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-27T09:39:55', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd56c27ae-cbd0-4d65-89d2-515ed99fc57f'	System	27 Dec 2020 14:40:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 14:40:10

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-27T09:39:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'd56c27ae-cbd0-4d65-89d2-515ed99fc57f' User entered '27 Dec 2020 09:39:57'	System	27 Dec 2020 14:40:10

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-31T08:28:34', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a91db07e-ceab-42c1-99a4-4b0d35fd1928' User entered 'No (N)'	System	31 Dec 2020 13:28:40
	System	31 Dec 2020 13:28:40

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-31T08:28:36', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a91db07e-ceab-42c1-99a4-4b0d35fd1928' User entered 'No (N)'	System	31 Dec 2020 13:28:40
	System	31 Dec 2020 13:28:40



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2020-12-31T08:28:38', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a91db07e-ceab-42c1-99a4-4b0d35fd1928' User entered '31 Dec 2020 08:28:38'	System	31 Dec 2020 13:28:40
	System	31 Dec 2020 13:28:40

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:19:51

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-07T09:51:14', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b5c2b7e-da8c-48ca-b14a-93df96bfd973' User entered 'Yes (Y)'	System	07 Jan 2021 14:51:46
	System	07 Jan 2021 14:51:46

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-07T09:51:18', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b5c2b7e-da8c-48ca-b14a-93df96bfd973' User entered 'No (N)'	System	07 Jan 2021 14:51:46
	System	07 Jan 2021 14:51:46

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-07T09:51:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b5c2b7e-da8c-48ca-b14a-93df96bfd973' User entered 'No (N)'	System	07 Jan 2021 14:51:46

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-07T09:51:25', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b5c2b7e-da8c-48ca-b14a-93df96bfd973' User entered 'Yes (Y)'	System	07 Jan 2021 14:51:46
	System	07 Jan 2021 14:51:46



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Please 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-07T09:51:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b5c2b7e-da8c-48ca-b14a-93df96bfd973'	System	07 Jan 2021 14:51:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Jan 2021 14:51:46

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-07T09:51:31', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '6b5c2b7e-da8c-48ca-b14a-93df96bfd973' User entered '07 Jan 2021 09:51:31'	System	07 Jan 2021 14:51:46
	System	07 Jan 2021 14:51:46

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-15T04:56:52', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e54a9f06-2dc1-44b3-ae43-074f3e1d245f' User entered 'No (N)'	System	15 Jan 2021 09:56:58
	System	15 Jan 2021 09:56:58

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-15T04:56:53', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e54a9f06-2dc1-44b3-ae43-074f3e1d245f' User entered 'No (N)'	System	15 Jan 2021 09:56:58
	System	15 Jan 2021 09:56:58

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-15T04:56:56', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e54a9f06-2dc1-44b3-ae43-074f3e1d245f' User entered '15 Jan 2021 04:56:56'	System	15 Jan 2021 09:56:58
	System	15 Jan 2021 09:56:58



US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-21T08:24:40', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'bc356727-d9ca-4a2a-af2f-1af5fd52fc75'	System	21 Jan 2021 13:24:47
User entered 'No (N)'	System	21 Jan 2021 13:24:47

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-21T08:24:41', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'bc356727-d9ca-4a2a-af2f-1af5fd52fc75'	System	21 Jan 2021 13:24:47
User entered 'No (N)'	System	21 Jan 2021 13:24:47

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-21T08:24:44', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'bc356727-d9ca-4a2a-af2f-1af5fd52fc75' User entered '21 Jan 2021 08:24:44'	System	21 Jan 2021 13:24:47

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-29T14:46:04', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '4c714fe1-27df-48c6-87ae-1396c546a17e' User entered 'No (N)'	System	29 Jan 2021 19:46:14

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-29T14:46:06', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '4c714fe1-27df-48c6-87ae-1396c546a17e'	System	29 Jan 2021 19:46:14
User entered 'No (N)'	System	29 Jan 2021 19:46:14

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-01-29T14:46:08', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '4c714fe1-27df-48c6-87ae-1396c546a17e' User entered '29 Jan 2021 14:46:08'	System	29 Jan 2021 19:46:14
	System	29 Jan 2021 19:46:14

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-08T16:36:56', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '19d907b4-a66c-494f-8789-ecc382f6afb0' User entered 'No (N)'	System	08 Feb 2021 21:37:04
	System	08 Feb 2021 21:37:04



US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-08T16:36:58', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '19d907b4-a66c-494f-8789-ecc382f6afb0' User entered 'No (N)'	System	08 Feb 2021 21:37:04
	System	08 Feb 2021 21:37:04

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-08T16:37:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '19d907b4-a66c-494f-8789-ecc382f6afb0' User entered '08 Feb 2021 16:37:00'	System	08 Feb 2021 21:37:04
	System	08 Feb 2021 21:37:04

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-14T11:40:20', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9fa179ef-728d-41bd-a5f7-40f99d294cb6'	System	14 Feb 2021 16:40:31
User entered 'No (N)'	System	14 Feb 2021 16:40:31

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-14T11:40:25', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9fa179ef-728d-41bd-a5f7-40f99d294cb6' User entered 'No (N)'	System	14 Feb 2021 16:40:31

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-14T11:40:27', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '9fa179ef-728d-41bd-a5f7-40f99d294cb6' User entered '14 Feb 2021 11:40:27'	System	14 Feb 2021 16:40:31
	System	14 Feb 2021 16:40:31



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-18T09:05:57', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e769e8d9-2a8e-4aa9-9c24-afb6a7ee98d3'	System	18 Feb 2021 14:06:16
User entered 'No (N)'	System	18 Feb 2021 14:06:16

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-18T09:06:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e769e8d9-2a8e-4aa9-9c24-afb6a7ee98d3'	System	18 Feb 2021 14:06:16
User entered 'Yes (Y)'	System	18 Feb 2021 14:06:16

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Please 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-18T09:06:02', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e769e8d9-2a8e-4aa9-9c24-afb6a7ee98d3'	System	18 Feb 2021 14:06:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 14:06:16

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-18T09:06:07', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'e769e8d9-2a8e-4aa9-9c24-afb6a7ee98d3' User entered '18 Feb 2021 09:06:07'	System	18 Feb 2021 14:06:16
	System	18 Feb 2021 14:06:16

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:12-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered 'Yes (Y)'	System	28 Feb 2021 04:49:29
	System	28 Feb 2021 04:49:29

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:16-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered 'No (N)'	System	28 Feb 2021 04:49:29
	System	28 Feb 2021 04:49:29

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:22-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered 'Yes (Y)'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '0'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '0'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '0'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '0'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '0'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '0'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '0'	System	28 Feb 2021 04:49:29



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered '1'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:39-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '0'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Please 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:41-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 04:49:29

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:45-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered 'Yes (Y)'	System	28 Feb 2021 04:49:29



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Please 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:47-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74'	System	28 Feb 2021 04:49:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:49-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'a31edc8c-3999-4bd0-9e82-12061c7baa74' User entered '28 Feb 2021 04:48:49'	System	28 Feb 2021 04:49:29
	System	28 Feb 2021 04:49:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-05T11:51:10-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0cfc7156-6db9-40e6-988a-3b1adccc2a0c'	System	05 Mar 2021 16:51:20
User entered 'No (N)'	System	05 Mar 2021 16:51:20

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-05T11:51:14-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0cfc7156-6db9-40e6-988a-3b1adccc2a0c'	System	05 Mar 2021 16:51:20
User entered 'No (N)'	System	05 Mar 2021 16:51:20

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-05T11:51:16-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '0cfc7156-6db9-40e6-988a-3b1adccc2a0c' User entered '05 Mar 2021 11:51:16'	System	05 Mar 2021 16:51:20
	System	05 Mar 2021 16:51:20



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-11T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'cf8bbb2a-0075-4419-a6a7-b99ea6e4ad9b'	System	11 Mar 2021 05:03:53
User entered 'No (N)'	System	11 Mar 2021 05:03:53

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-11T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'cf8bbb2a-0075-4419-a6a7-b99ea6e4ad9b'	System	11 Mar 2021 05:03:53
User entered 'No (N)'	System	11 Mar 2021 05:03:53

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-11T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'cf8bbb2a-0075-4419-a6a7-b99ea6e4ad9b' User entered '11 Mar 2021 00:02:31'	System	11 Mar 2021 05:03:53
	System	11 Mar 2021 05:03:53

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-18T18:56:23-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '247be6c9-4b21-4b5e-8b55-e62a952c9a03'	System	18 Mar 2021 22:56:29
User entered 'No (N)'	System	18 Mar 2021 22:56:29

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-18T18:56:25-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '247be6c9-4b21-4b5e-8b55-e62a952c9a03'	System	18 Mar 2021 22:56:29
User entered 'No (N)'	System	18 Mar 2021 22:56:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-18T18:56:27-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '247be6c9-4b21-4b5e-8b55-e62a952c9a03'	System	18 Mar 2021 22:56:29
User entered '18 Mar 2021 18:56:27'	System	18 Mar 2021 22:56:29

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-26T09:38:23-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7d0e6302-cba4-4b75-971c-6e5c8d1444e2'	System	26 Mar 2021 13:38:36
User entered 'No (N)'	System	26 Mar 2021 13:38:36



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-26T09:38:24-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7d0e6302-cba4-4b75-971c-6e5c8d1444e2'	System	26 Mar 2021 13:38:36
User entered 'No (N)'	System	26 Mar 2021 13:38:36

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-03-26T09:38:27-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '7d0e6302-cba4-4b75-971c-6e5c8d1444e2' User entered '26 Mar 2021 09:38:27'	System	26 Mar 2021 13:38:36
	System	26 Mar 2021 13:38:36

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-01T08:12:33-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '54137828-1a3d-48e1-81ac-da35057e1517'	System	01 Apr 2021 12:12:40
User entered 'No (N)'	System	01 Apr 2021 12:12:40

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-01T08:12:35-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '54137828-1a3d-48e1-81ac-da35057e1517'	System	01 Apr 2021 12:12:40
User entered 'No (N)'	System	01 Apr 2021 12:12:40

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-01T08:12:37-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '54137828-1a3d-48e1-81ac-da35057e1517'	System	01 Apr 2021 12:12:40
User entered '01 Apr 2021 08:12:37'	System	01 Apr 2021 12:12:40



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-08T19:50:40-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1921f0ba-681d-4170-9ff5-897dfb3bf7ca' User entered 'No (N)'	System	08 Apr 2021 23:50:49
	System	08 Apr 2021 23:50:49

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-08T19:50:43-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1921f0ba-681d-4170-9ff5-897dfb3bf7ca'	System	08 Apr 2021 23:50:49
User entered 'No (N)'	System	08 Apr 2021 23:50:49

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-08T19:50:45-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '1921f0ba-681d-4170-9ff5-897dfb3bf7ca' User entered '08 Apr 2021 19:50:45'	System	08 Apr 2021 23:50:49
	System	08 Apr 2021 23:50:49

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-18T16:00:36-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '39b54b22-4758-4d75-aed7-d558812b4df3'	System	18 Apr 2021 20:00:54
User entered 'No (N)'	System	18 Apr 2021 20:00:54

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-18T16:00:38-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '39b54b22-4758-4d75-aed7-d558812b4df3'	System	18 Apr 2021 20:00:54
User entered 'No (N)'	System	18 Apr 2021 20:00:54

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-18T16:00:41-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '39b54b22-4758-4d75-aed7-d558812b4df3'	System	18 Apr 2021 20:00:54
User entered '18 Apr 2021 16:00:41'	System	18 Apr 2021 20:00:54

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-22T00:02:21-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '15b68f0b-a457-473e-a00e-e142d2274ceb' User entered 'No (N)'	System	22 Apr 2021 04:02:59
	System	22 Apr 2021 04:02:59



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-22T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '15b68f0b-a457-473e-a00e-e142d2274ceb' User entered 'No (N)'	System	22 Apr 2021 04:02:59

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-22T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '15b68f0b-a457-473e-a00e-e142d2274ceb' User entered '22 Apr 2021 00:02:26'	System	22 Apr 2021 04:02:59
	System	22 Apr 2021 04:02:59

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-29T04:26:10-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84d9f1b1-b499-46c5-b997-0880b9cce0d3' User entered 'No (N)'	System	29 Apr 2021 08:26:21
	System	29 Apr 2021 08:26:21

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Have you been exposed to someone with 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 (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-29T04:26:13-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84d9f1b1-b499-46c5-b997-0880b9cce0d3'	System	29 Apr 2021 08:26:21
User entered 'No (N)'	System	29 Apr 2021 08:26:21

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-04-29T04:26:15-04:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: '84d9f1b1-b499-46c5-b997-0880b9cce0d3'	System	29 Apr 2021 08:26:21
User entered '29 Apr 2021 04:26:15'	System	29 Apr 2021 08:26:21



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:19:51

US3182025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:19:51

US3182025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:19:51



**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:19:51

**US3182025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:35:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:19:51
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:19:51



US3182025

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:35:54**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:42:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:53-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b0d608e1-67ba-45cf-aa17-aa74d0371d17'	System	28 Feb 2021 04:49:40
User entered 'No (N)'	System	28 Feb 2021 04:49:40

US3182025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:35:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:42:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3DA40F9E-5FF6-4BD1-8916-F6FAFEF85623)', Time: '2021-02-27T23:48:55-05:00', User OID: 'PatientReportedOutcome (US3182025)', ODM File OID: 'b0d608e1-67ba-45cf-aa17-aa74d0371d17' User entered '28 Feb 2021 04:48:55'	System	28 Feb 2021 04:49:40
	System	28 Feb 2021 04:49:40

US3182025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:37:28

US3182025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '16 Oct 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:37:28

US3182025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:37:28

US3182025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	22 Oct 2020 17:37:28
	(b) (4)	

US3182025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:37:13

US3182025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:30
User entered 'I'	System	22 Oct 2020 17:37:13



US3182025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 15:29:01

US3182025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '23 Nov 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 15:29:01

US3182025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 15:29:01

US3182025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Nov 2020 15:29:01
	(b) (4)	

US3182025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 15:29:08

US3182025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered 'I'	System	25 Nov 2020 15:29:08

US3182025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	22 Dec 2020 18:19:22

US3182025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '21 Dec 2020'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	22 Dec 2020 18:19:22



US3182025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	22 Dec 2020 18:19:22

US3182025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4) Gabby Jacobs (b) (4) (b) (4)	22 Dec 2020 18:19:22

US3182025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	22 Dec 2020 18:19:29

US3182025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered 'I'	System	22 Dec 2020 18:19:29

US3182025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	18 Jan 2021 18:35:13

US3182025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 09FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 06:44:35
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 09FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:29:37
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 09FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 08:40:27
User entered '18 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	18 Jan 2021 18:35:13

US3182025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	18 Jan 2021 18:35:13

US3182025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	18 Jan 2021 18:35:13
	(b) (4)	



US3182025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 07:46:49
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:29:13
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 09:28:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Jan 2021 18:35:18

US3182025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered 'I'	System	18 Jan 2021 18:35:18

US3182025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User closed query '?????Per CDM: Visit 4 Day 209 a Participant Decision Visit / OL-D1 are both dated 09FEB2021. However, the data on the Immunogenicity Assessment forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).		01 Apr 2021 10:55:20
Query '?????Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 09FEB2021. However, the data on the Immunogenicity Assessment forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:19:13
User opened query '?????Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 09FEB2021. However, the data on the Immunogenicity Assessment forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:25:24
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:30:29

US3182025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '09 Feb 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:30:29
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[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 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:30:29

US3182025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered 'VISIT4'	System	02 Mar 2021 15:30:29

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	



US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered empty.	System	31 Mar 2021 13:18:49

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered empty.	System	31 Mar 2021 13:18:49

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	



US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered empty.	System	31 Mar 2021 13:18:49

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered empty.	System	31 Mar 2021 13:18:49

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:18:49
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered empty.	System	31 Mar 2021 13:18:49

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50

US3182025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50

US3182025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:19:07
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	31 Mar 2021 13:19:07
	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 15:30:35
	(b) (4)	



US3182025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:52:29
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:19:07
	(b) (4)	
User entered '09 Feb 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	31 Mar 2021 13:19:07
	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Mar 2021 15:30:35
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:30:47
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '09 Feb 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:30:47
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '10:19'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:30:47
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered '09 Feb 2021 10:19'	System	02 Mar 2021 15:30:47

US3182025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:30:52
	(b) (4)	

US3182025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:33:50
User entered 'I'	System	02 Mar 2021 15:30:52

US3182025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:31:46
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
User entered 'Yes (Y)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	30 Mar 2021 13:20:01



US3182025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:31:46
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
User entered '24 Mar 2021'	(b) (4) Brooke Glivar (b) (4) (b) (4)	30 Mar 2021 13:20:01

US3182025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:31:46
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	30 Mar 2021 13:20:01

US3182025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:31:46
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
User entered empty.	(b) (4)	
	Brooke Glivar (b) (4)	30 Mar 2021 13:20:01
	(b) (4)	

US3182025

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:31:46
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
User entered 'Yes (Y)'	(b) (4)	
	Brooke Glivar (b) (4)	30 Mar 2021 13:20:04
	(b) (4)	

US3182025

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:31:46
User entered 'I'	System	30 Mar 2021 13:20:04

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:31:54
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '09 Feb 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:31:54
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:31:54



US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User entered 'UNBLND_DECIDE'	System	02 Mar 2021 15:31:54

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '09 Feb 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:39
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:33
User entered '0'	(b) (4) Naqib Ahmad (b) (4)	09 Apr 2021 17:42:01
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 16:09:52

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:39
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).		14 Apr 2021 12:53:05
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	09 Apr 2021 17:43:33
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'Updated.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	09 Apr 2021 17:42:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	Naqib Ahmad (b) (4) (b) (4)	09 Apr 2021 17:42:01
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:32:18
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:09:52

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '09 Feb 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:39
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:32:39

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:32:39



US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:32:39

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 15:32:39
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User entered empty.	System	02 Mar 2021 15:32:39

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User entered empty.	System	02 Mar 2021 15:32:39

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:20
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '09 Feb 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:20
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '10:25'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:20
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User entered '09 Feb 2021 10:25'	System	02 Mar 2021 15:32:20



US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 15:32:04

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '09 Feb 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:04
	(b) (4)	

US3182025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '10:19'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 15:32:04
	(b) (4)	

**US3182025**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:35:54**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:13:18
User entered '09 Feb 2021 10:19'	System	02 Mar 2021 15:32:04

US3182025

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:35:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:47
DataPoint Verified.		14 Apr 2021 18:35:27
User closed query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).		31 Mar 2021 15:38:42
Query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject marked in error' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 16:07:04
User opened query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 13:59:11
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:01:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:26:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Feb 2021 16:17:19

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:35:54**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:29
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:58:05
User entered 'USA-US075-2021-mRNA-1273-P301000010'	System	25 Mar 2021 15:58:01
User entered 'New'	(b) (4), (b) (6)	25 Mar 2021 15:58:01

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:31
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysfunctional uterine bleeding, LLT: Dysfunctional uterine bleeding - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 21:28:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:28:55
Data point term sent to Coder	System	19 Feb 2021 21:28:18
User entered 'Dysfunctional Uterine Bleeding'	Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:34
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'No (N)'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:41
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'No (N)'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:44
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:52:42
	(b) (4)	
User entered '20 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	23 Mar 2021 19:52:42
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered '14 Dec 2020'	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:46
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:35:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:47
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'No (N)'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:49
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:52:42
	(b) (4)	
User entered '08 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	23 Mar 2021 19:52:42
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Feb 2021 21:28:33
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	19 Feb 2021 21:28:33
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	19 Feb 2021 21:27:59
User entered '17 Jan 2021'	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:39:53
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	



**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:35:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 20:00:01
User closed query 'Per completion guidelines severity should be 4 since they were hospitalized. Please update as appropriate. ' (Site from CRA).	(b) (4)	22 Apr 2021 17:05:23
Query 'Per completion guidelines severity should be 4 since they were hospitalized. Please update as appropriate. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4)	22 Apr 2021 16:37:07
Signature has been broken.	Jennifer Gaston (b) (4)	22 Apr 2021 16:36:57
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	22 Apr 2021 16:36:57
User opened query 'Per completion guidelines severity should be 4 since they were hospitalized. Please update as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:40:34
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
Signature has been broken.	(b) (4) Naqib Ahmad (b) (4)	24 Mar 2021 20:22:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	24 Mar 2021 20:22:28
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:47
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:49
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).		02 Apr 2021 07:51:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
	(b) (4)	
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 'Updated' (Site from System).	Cassie Uminski (b) (4)	26 Mar 2021 15:56:15
	(b) (4)	
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	24 Mar 2021 20:22:28
Signature has been broken.	Naqib Ahmad (b) (4)	24 Mar 2021 20:22:28
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	24 Mar 2021 20:22:28
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:55:57
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 15:55:57
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:55:57
	(b) (4)	
User entered '08 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 15:55:57
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:52
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:54
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:56
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:40:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:01
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:09
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:10
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:12
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:43:06
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:43:52
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'I'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:43:54
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'I'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:43:57
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Jennifer Gaston (b) (4)	19 Feb 2021 21:28:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:43:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:01
User closed query 'Per DM CLR: Narrative = SHE COMPLAINED OF LIGHTHEADEDNESS WITH STANDING, DIZZINESS AND INABILITY TO STAY AWAKE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 22:36:55
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:51:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:51:31
Query 'Per DM CLR: Narrative = SHE COMPLAINED OF LIGHTHEADEDNESS WITH STANDING, DIZZINESS AND INABILITY TO STAY AWAKE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'Will update separate AE accordingly.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:09:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Will redact and send.' (Site from Safety).	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:04:03

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'After further review of medical records, subject did not have any testing for Covid-19 performed. ' (Site from Safety).	Naqib Ahmad (b) (4)	06 Apr 2021 20:03:38
User opened query 'Per DM CLR: Narrative = SHE COMPLAINED OF LIGHTHEADEDNESS WITH STANDING, DIZZINESS AND INABILITY TO STAY AWAKE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:11:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		02 Apr 2021 17:54:23
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		02 Apr 2021 17:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Mar 2021 16:02:18
Signature has been broken.	System	26 Mar 2021 16:02:18
	Cassie Uminski (b) (4)	26 Mar 2021 16:02:18
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject underwent a hysteroscopy with D&C and removal of IUD on 1/7/21 for abnormal uterine bleeding resulting in severe anemia unrelieved with OCP's and depo provera , now with HCT 21 after blood transfusion one week prior to surgery. Pelvic US was significant for a retained IUD placed in Israel 3 years ago and with unsuccessful in-Office attempt at removal. Surgery was uncomplicated, however she was given 2 untis of pRBC's intraoperatively. In PACU, she complained of lightheadedness with standing, dizziness and inability to stay awake, as well as lower abdominal cramping. She was kept overnight for observation due to her symptoms, known anemia, and receipt of blood transfusion intraoperatively.' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 16:02:18
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Mar 2021 20:22:28
User signature succeeded.	Mary Beth Manning (b) (4)	11 Mar 2021 22:10:23
User entered empty.	Jennifer Gaston (b) (4)	19 Feb 2021 21:27:59



**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 20:22:28
User entered '0'	System	19 Feb 2021 21:27:59

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 21:27:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 19:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 19:55:40
Data point term sent to Coder	System	23 Mar 2021 19:55:27
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:51
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:51
User entered 'Iron deficiency ANEMIA' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:51
User signature succeeded.	Mary Beth Manning (b) (4)	11 Mar 2021 22:10:23
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Blood loss anaemia, LLT: Blood loss anaemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 20:42:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 20:42:05
Data point term sent to Coder	System	19 Feb 2021 21:33:25
User entered 'Anemia due to blood loss'	Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
	(b) (4)	
User entered '24 Dec 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
User signature succeeded.	(b) (4)	
	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered '20 Dec 2020'	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User entered empty.	System	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
	(b) (4)	
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
	(b) (4)	
Signature has been broken.	Naqib Ahmad (b) (4)	06 Apr 2021 20:24:09
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	06 Apr 2021 20:24:09
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
	(b) (4)	
User entered '06 Apr 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
User signature succeeded.	(b) (4)	
	Mary Beth Manning	07 Apr 2021 15:43:57
	(b) (4)	
Signature has been broken.	Naqib Ahmad (b) (4)	06 Apr 2021 20:24:09
	(b) (4)	
User entered empty; reason for change Data Entry Error	Naqib Ahmad (b) (4)	06 Apr 2021 20:24:09
User signature succeeded.	(b) (4)	
	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
Signature has been broken.	Cassie Uminski (b) (4)	23 Mar 2021 19:50:35
	(b) (4)	
User entered '08 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	23 Mar 2021 19:50:35
User signature succeeded.	(b) (4)	
	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered '17 Jan 2021'	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User entered empty.	System	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User closed query 'Should this be yes? Page 113 of hospital records admitted for observation overnight due to symptomatic anemia. ' (Site from CRA).		01 Apr 2021 23:02:22
Query 'Should this be yes? Page 113 of hospital records admitted for observation overnight due to symptomatic anemia. ' answered with 'The anemia was caused from the DUB per investigator making the DUB the SAE.' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 16:03:15
User opened query 'Should this be yes? Page 113 of hospital records admitted for observation overnight due to symptomatic anemia. ' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 14:47:14
User signature succeeded.	Mary Beth Manning (b) (4)	11 Mar 2021 22:10:23
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59



US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59



US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
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	19 Feb 2021 21:33:13
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	19 Feb 2021 21:33:13
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Gaston (b) (4)	19 Feb 2021 21:33:13
User entered empty.	(b) (4)	
	System	19 Feb 2021 21:32:59
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User closed query 'Per CDM: Please keep the query opened until the records are updated .Thank You.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:50:54
Query 'Per CDM: Please keep the query opened until the records are updated .Thank You.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:47:44
User opened query 'Per CDM: Please keep the query opened until the records are updated .Thank You.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 18:14:14
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 18:13:01
User signature succeeded.	Mary Beth Manning (b) (4)	11 Mar 2021 22:10:23
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Pending medical records - followed up on today, still no documents received. Subjects states she was transfused blood products to correct anemia. Will update as soon as further records received.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	11 Mar 2021 17:31:07
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 02:22:01
User entered 'I'	Jennifer Gaston (b) (4) (b) (4)	19 Feb 2021 21:32:59

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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).		13 Apr 2021 22:37:36
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Subject received packed RBC's, which is a con-med.' (Site from DM).	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 19:50:42
Signature has been broken.	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 19:50:18
User entered '0' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 19:50:18
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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) (4), (b) (6)	03 Apr 2021 05:11:57
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	23 Mar 2021 19:54:51
User entered '1' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	23 Mar 2021 19:54:51
User signature succeeded.	(b) (4) Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1823 of 2755



US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cassie Uminski (b) (4)	08 Apr 2021 16:21:34
Data Entry Error	(b) (4)	
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
	(b) (4)	
Signature has been broken.	Naqib Ahmad (b) (4)	06 Apr 2021 20:24:09
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Naqib Ahmad (b) (4)	06 Apr 2021 20:24:09
Data Entry Error	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	19 Feb 2021 21:32:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User entered '0'	System	19 Feb 2021 21:32:59

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16
User entered '1'	System	19 Feb 2021 21:32:59

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:16

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Vulvovaginal mycotic infection, LLT: Vaginal yeast infection - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 16:23:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 16:23:54
Data point term sent to Coder	System	08 Apr 2021 16:22:22
Coding entries removed.	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
Signature has been broken.	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
User entered 'Vaginal YEAST INFECTION' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Female reproductive tract infections, PT: Uterine infection, LLT: Uterine infection - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 13:18:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 13:18:56
User signature succeeded.	Mary Beth Manning (b) (4)	11 Mar 2021 22:10:23
Data point term sent to Coder	System	02 Mar 2021 18:36:19
User entered 'Uterine Yeast infection'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59



US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '15 Jan 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User entered empty.	System	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User entered '25 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	



**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User entered empty.	System	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59



US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User entered 'None (NONE)' reason for change:	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
Data Entry Error	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered 'I'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:35:59

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cassie Uminski (b) (4)	08 Apr 2021 16:22:12
Data Entry Error	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:10:23
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:35:59
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User entered '0'	System	02 Mar 2021 18:35:59



**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17
User entered '1'	System	02 Mar 2021 18:35:59

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:17

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Thrombophlebitis, LLT: Thrombophlebitis arm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:16:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:16:34
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
Data point term sent to Coder	System	23 Mar 2021 19:54:26
User entered 'Thrombophlebitis-Left Arm'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
Signature has been broken.	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 20:28:58
User entered '28 Dec 2020' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 20:28:58
User signature succeeded.	(b) (4) Mary Beth Manning	23 Mar 2021 23:36:17
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11



US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User entered empty.	System	23 Mar 2021 19:54:11

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:35:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 16:24:37
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Apr 2021 16:24:37
	(b) (4)	
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
	(b) (4)	
Signature has been broken.	Naqib Ahmad (b) (4)	06 Apr 2021 20:28:58
	(b) (4)	
User entered '04 Jan 2021' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	06 Apr 2021 20:28:58
	(b) (4)	
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered '29 Dec 2020'	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User entered empty.	System	23 Mar 2021 19:54:11

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:35:54**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11



**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:35:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11



US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'I'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11



US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:54:11
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User entered '0'	System	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11
User entered '1'	System	23 Mar 2021 19:54:11

US3182025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:31:11

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal cramp - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 19:48:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	06 Apr 2021 19:48:23
Data point term sent to Coder	System	06 Apr 2021 19:47:55
Coding entries removed.	Naqib Ahmad (b) (4)	06 Apr 2021 19:47:54
Signature has been broken.	(b) (4)	06 Apr 2021 19:47:54
User entered 'ABDOMINAL Cramping' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	06 Apr 2021 19:47:54
User signature succeeded.	(b) (4)	23 Mar 2021 23:36:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:56:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	23 Mar 2021 19:56:41
Data point term sent to Coder	System	23 Mar 2021 19:56:28
User entered 'Abdominal Pain'	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '13 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered empty.	System	23 Mar 2021 19:56:21

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21



US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered empty.	System	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21



US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21



US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'I'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:56:21
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered '0'	System	23 Mar 2021 19:56:21



**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered '1'	System	23 Mar 2021 19:56:21

US3182025

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 19:59:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 19:59:40
Data point term sent to Coder	System	23 Mar 2021 19:58:33
User entered 'Nausea'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '13 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered empty.	System	23 Mar 2021 19:58:17

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered empty.	System	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17



**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17



US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Mar 2021 20:00:21
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'I'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17



US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 19:58:17

US3182025

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 19:58:17
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered '0'	System	23 Mar 2021 19:58:17

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27
User entered '1'	System	23 Mar 2021 19:58:17

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:27

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:35:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User closed query 'Please clarify as page 2 of hospital records has denies any episodes of vomiting. ' (Site from CRA).	(b) (4)	31 Mar 2021 14:07:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
Query 'Please clarify as page 2 of hospital records has denies any episodes of vomiting. ' answered with 'Updated' (Site from CRA).	(b) (4)	26 Mar 2021 15:45:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Cassie Uminski (b) (4)	26 Mar 2021 15:44:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 15:44:27
Data point term sent to Coder	System	26 Mar 2021 15:44:18
Coding entries removed.	Cassie Uminski (b) (4)	26 Mar 2021 15:44:15
Signature has been broken.	(b) (4)	26 Mar 2021 15:44:15
User entered 'Diarrhea' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 15:44:15
User opened query 'Please clarify as page 2 of hospital records has denies any episodes of vomiting. ' (Site from CRA).	(b) (4)	25 Mar 2021 15:09:34
User signature succeeded.	(b) (4), (b) (6)	
	Mary Beth Manning	23 Mar 2021 23:36:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	(b) (4)	23 Mar 2021 20:01:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 20:01:47
Data point term sent to Coder	System	23 Mar 2021 20:00:35
User entered 'Vomiting'	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '13 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User entered empty.	System	23 Mar 2021 20:00:07

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User entered empty.	System	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07



US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
Signature has been broken.	System	06 Apr 2021 19:54:21
	Naqib Ahmad (b) (4)	06 Apr 2021 19:54:21
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Naqib Ahmad (b) (4)	06 Apr 2021 19:54:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User signature succeeded.	System	06 Apr 2021 19:52:05
	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		13 Apr 2021 22:39:06
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Subject did not receive any medications for diarrhea. ' (Site from DM).	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:54:52
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:52:05
User entered '0' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:52:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:12:11
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '1'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:00:07

US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	23 Mar 2021 20:00:07
	(b) (4)	

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User entered '0'	System	23 Mar 2021 20:00:07



US3182025

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:35:54

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32
User entered '1'	System	23 Mar 2021 20:00:07

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:32

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:35:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 20:15:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:15:25
Data point term sent to Coder	System	06 Apr 2021 20:14:55
User entered 'Dizziness'	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'Yes (Y)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '07 Jan 2021'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15



US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User entered empty.	System	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '08 Jan 2021'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User entered empty.	System	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15



US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15



US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'Not Related (NOT RELATED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'Not Related (NOT RELATED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
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	06 Apr 2021 20:14:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	06 Apr 2021 20:14:33
User opened query 'Data is required. Please complete.' (Site from System).	Naqib Ahmad (b) (4)	06 Apr 2021 20:14:33
User entered empty.	(b) (4)	
	System	06 Apr 2021 20:14:15
	Naqib Ahmad (b) (4)	06 Apr 2021 20:14:15
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'I'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15



US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User entered '0'	System	06 Apr 2021 20:14:15

US3182025

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:35:54

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54
User entered '1'	System	06 Apr 2021 20:14:15

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:35:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:22:54

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:35:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 16:27:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 16:27:55
Data point term sent to Coder	System	08 Apr 2021 16:26:28
User entered 'Abdominal Pain'	Cassie Uminski (b) (4)	08 Apr 2021 16:26:25



US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '28 Dec 2020'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User entered empty.	System	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '28 Dec 2020'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User entered empty.	System	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered '0'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered '0'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25



US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered '0'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25



US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered '0'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'I'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:26:25
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User entered '0'	System	08 Apr 2021 16:26:25



US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00
User entered '1'	System	08 Apr 2021 16:26:25

US3182025

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:00

**US3182025**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:35:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Pain NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:44:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:44:54
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
Data point term sent to Coder	System	08 Apr 2021 16:30:32
User entered 'Unspecified Pain'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User entered empty.	System	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User entered empty.	System	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered 'I'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered '0'	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	



US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:14:41
User entered empty.	(b) (4) Cassie Uminski (b) (4)	08 Apr 2021 16:29:45
	(b) (4)	

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	08 Apr 2021 17:14:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User entered '0'	System	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01
User entered '0'	System	08 Apr 2021 16:29:45

US3182025

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:23:01

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:35:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:47
DataPoint Verified.		12 Apr 2021 15:35:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:15:59

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:36
Data point term sent to Coder	System	29 Jul 2020 14:17:23
User entered 'Zyrtec'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:16:50



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '10'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 15:42:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:20:39
answered with 'Subject is currently taking this medication, please advise.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 14:16:50
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:16:50

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:16:50
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 14:16:50

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 14:16:50



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 14:16:50

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Oct 2020 14:10:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 14:10:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:06:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:06:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 13:59:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 13:59:01
Data point term sent to Coder	System	29 Jul 2020 14:18:23
User entered 'Fluticasone'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:17:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '50'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'ug (ug)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 15:42:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:20:35
answered with 'Subject is currently taking this medication, please advise.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 14:17:28
User entered 'un UNK 2018'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:17:28

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:28
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Jul 2020 14:17:28

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 14:17:28

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 14:17:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:31
Data point term sent to Coder	System	29 Jul 2020 14:18:23
User entered 'Vitamin D'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:17:55

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 15:43:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:20:30
answered with 'Subject is currently taking this medication, please advise.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 14:17:55
User entered 'un UNK 2015'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:17:55

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:17:55
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 14:17:55

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 14:17:55

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 14:17:55

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: INTRAUTERINE CONTRACEPTIVE DEVICE, PRODUCTSYNONYM: IUD NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:12:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:12:14
Data point term sent to Coder	System	05 Oct 2020 14:56:42
User closed query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	System	05 Oct 2020 14:55:59
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' answered with 'Unknown' (Site from System).	Cassie Uminski (b) (4)	05 Oct 2020 14:55:59
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4)	18 Aug 2020 11:34:16
Data point term sent to Coder	System	29 Jul 2020 14:19:24
User entered 'Non hormonal IUD'	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Birth control'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'I'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:18:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Other (OTHER)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:18:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'application'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:18:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).		26 Apr 2021 13:46:51
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'confirmed correct as is, subject has only 1 application ' (Site from System).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 16:39:53
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Apr 2021 16:38:46
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:01:52
User entered 'once (ONCE)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:18:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Other (OTHER)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:18:53

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Intrauterine'	(b) (4) Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:18:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 15:43:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:20:25
answered with 'Subject is currently taking this medication, please advise.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 14:18:53
User entered 'un UNK 2017'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:18:53



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 20:00:01
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 16:38:46
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	22 Apr 2021 16:38:46
	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 20:00:01
User closed query 'Should the end date be 07Jan2021 as it appears to have been removed at that point? ' (Site from CRA).	(b) (4)	
Query 'Should the end date be 07Jan2021 as it appears to have been removed at that point? ' answered with 'confirmed and updated' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:08:48
Signature has been broken.	Jennifer Gaston (b) (4)	22 Apr 2021 16:38:56
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	22 Apr 2021 16:38:46
User opened query 'Should the end date be 07Jan2021 as it appears to have been removed at that point? ' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 18:50:44
User entered empty.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	29 Jul 2020 14:18:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User entered empty.	System	29 Jul 2020 14:18:53

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User entered empty.	System	29 Jul 2020 14:18:53

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:21
User entered empty.	System	29 Jul 2020 14:18:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Please clarify if this should be NuvaRing instead of Niva Ring. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:23:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:26:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:26:40
Data point term sent to Coder	System	20 Nov 2020 14:42:16
Query 'Please clarify if this should be NuvaRing instead of Niva Ring. ' answered with 'updated' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	20 Nov 2020 14:41:56
Coding entries removed.	Naqib Ahmad (b) (4) (b) (4)	20 Nov 2020 14:41:49
User entered 'NUVARING' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	20 Nov 2020 14:41:49
User opened query 'Please clarify if this should be NuvaRing instead of Niva Ring. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:34:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:44:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:44:11
Data point term sent to Coder	System	29 Jul 2020 14:20:25
User entered 'Niva Ring'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:20:02



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Birth Control'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Application'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'every month (QM)'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Vaginal (VAGINAL)'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 15:43:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:20:20
answered with 'Subject is currently taking this medication, please advise.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 14:20:02
User entered '15 Jun 2020'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 14:20:02

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Jul 2020 14:20:02
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 14:20:02

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 14:20:02



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	29 Jul 2020 14:20:02

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 14:58:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 14:58:19
Data point term sent to Coder	System	05 Oct 2020 14:57:45
User entered 'Tylenol'	Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:56:50

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	05 Oct 2020 14:56:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Fever/Headache'	Cassie Uminski (b) (4)	05 Oct 2020 14:56:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '500'	(b) (4)	
	Cassie Uminski (b) (4)	05 Oct 2020 14:56:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:56:50

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	05 Oct 2020 14:56:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:56:50



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	05 Oct 2020 14:56:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Oral (ORAL)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:56:50

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	05 Oct 2020 14:56:50
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '24 Aug 2020'	(b) (4)	
	Cassie Uminski (b) (4)	05 Oct 2020 14:56:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:56:50

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Oct 2020 14:56:50
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '25 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:56:50

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 08:13:39
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE did not meet the AE reporting criteria.' answered with 'Does not meet AE reporting criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 13:30:26



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE did not meet the AE reporting criteria.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 13:58:12
	Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:56:50

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User entered empty.	System	05 Oct 2020 14:56:50

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User entered empty.	System	05 Oct 2020 14:56:50

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:47
User entered empty.	System	05 Oct 2020 14:56:50

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 11:31:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 11:31:24
Data point term sent to Coder	System	06 Apr 2021 20:19:02
User closed query 'CDM-Coding: Please enter the active ingredient(s) of drug name EXCEDRIN in drug name field and please make your changes to the reported term. Thank you.	System	06 Apr 2021 20:18:02
' (Site from System).		
Query 'CDM-Coding: Please enter the active ingredient(s) of drug name EXCEDRIN in drug name field and please make your changes to the reported term. Thank you.	Naqib Ahmad (b) (4)	06 Apr 2021 20:18:02
' answered with 'updated.' (Site from System).		
Data point term sent to Coder	System	06 Apr 2021 20:18:00
Coding entries removed.	Naqib Ahmad (b) (4)	06 Apr 2021 20:17:52
Signature has been broken.	Naqib Ahmad (b) (4)	06 Apr 2021 20:17:52
User entered 'EXCedrin (acetaminophen, aspirin, and caffeine)' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	06 Apr 2021 20:17:52
User opened query 'CDM-Coding: Please enter the active ingredient(s) of drug name EXCEDRIN in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4)	06 Apr 2021 11:20:46
' (Site from System).		
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:01:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:15:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:15:24
Data point term sent to Coder	System	05 Oct 2020 14:57:48
User entered 'Excedrin'	Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:57:27

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:57:27

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Fever/Headache'	Cassie Uminski (b) (4)	05 Oct 2020 14:57:27



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '250' reason for change: Data Entry Error	(b) (4) Amy Maroun (b) (4)	16 Oct 2020 13:21:40
User entered '1'	(b) (4) Cassie Uminski (b) (4)	05 Oct 2020 14:57:27
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Amy Maroun (b) (4)	16 Oct 2020 13:21:40
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	05 Oct 2020 14:57:27
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	05 Oct 2020 14:57:27
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:57:27

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	05 Oct 2020 14:57:27
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	05 Oct 2020 14:57:27

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	05 Oct 2020 14:57:27
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '24 Aug 2020'	Cassie Uminski (b) (4)	05 Oct 2020 14:57:27



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '0'	Cassie Uminski (b) (4)	05 Oct 2020 14:57:27

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 14:57:27

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '25 Aug 2020'	Cassie Uminski (b) (4)	05 Oct 2020 14:57:27

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 08:19:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE did not meet the AE reporting criteria.' answered with 'Does not meet AE reporting criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 13:31:09

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE did not meet the AE reporting criteria.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Cassie Uminski (b) (4) (b) (4)	05 Nov 2020 13:58:40 05 Oct 2020 14:57:27

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User entered empty.	System	05 Oct 2020 14:57:27

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User entered empty.	System	05 Oct 2020 14:57:27

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:31
User entered empty.	System	05 Oct 2020 14:57:27



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 18:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:38:45
Data point term sent to Coder	System	02 Mar 2021 18:37:20
User entered 'Docusate sodium'	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:36:58
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Prophylaxis'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '100'	(b) (4)	02 Mar 2021 18:36:58
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'mg (mg)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:36:58
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	02 Mar 2021 18:36:58
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	02 Mar 2021 18:36:58
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	02 Mar 2021 18:36:58
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '08 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '0'	Cassie Uminski (b) (4)	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:36:58
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '17 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 18:36:58

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User entered empty.	System	02 Mar 2021 18:36:58



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User entered empty.	System	02 Mar 2021 18:36:58

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:49
User entered empty.	System	02 Mar 2021 18:36:58

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 00:24:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 00:24:54
Data point term sent to Coder	System	02 Mar 2021 18:38:23
User entered 'Ibuprofen'	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:37:29

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Pain secondary to Dysfunctional uterine bleeding'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:37:29

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '600'	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:37:29

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:37:29

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'Oral (ORAL)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:37:29

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered empty.	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '08 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:37:29

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '0'	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered '17 Jan 2021'	(b) (4)	
	Cassie Uminski (b) (4)	02 Mar 2021 18:37:29
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User entered 'No (N)'	(b) (4)	02 Mar 2021 18:37:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User entered empty.	System	02 Mar 2021 18:37:29

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User entered empty.	System	02 Mar 2021 18:37:29

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:51:52
User entered empty.	System	02 Mar 2021 18:37:29

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE, PRODUCTSYNONYM: DIFLUCAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 08:34:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 08:34:54
Data point term sent to Coder	System	02 Mar 2021 18:38:23
User entered 'Diflucan'	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:37:53

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Uterine yeast infection'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '150'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '15 Jan 2021'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	02 Mar 2021 18:37:53
	(b) (4)	

**US3182025**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 18:37:53

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 18:37:53

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 18:37:53

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 05:22:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 05:22:25
Data point term sent to Coder	System	06 Apr 2021 19:44:47
Coding entries removed.	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:44:14
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:48:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:48:46
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
Data point term sent to Coder	System	23 Mar 2021 20:05:03
User entered 'Omnipaque 350'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:07:39
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Updated AE page to reflect this change. ' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:19:50
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:44:14
User entered 'Abdominal Cramping' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:44:14
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:49:44
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
User entered 'Nausea/vomiting'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '100'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'mL (mL)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:04:28
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	23 Mar 2021 20:11:41
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4)	23 Mar 2021 20:04:28
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:04:28
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:04:28
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	Cassie Uminski (b) (4)	23 Mar 2021 20:04:28

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	Cassie Uminski (b) (4)	23 Mar 2021 20:04:28

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User entered empty.	System	23 Mar 2021 20:04:28

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User entered empty.	System	23 Mar 2021 20:04:28

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:12
User entered empty.	System	23 Mar 2021 20:04:28



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 20:05:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 20:05:43
Data point term sent to Coder	System	23 Mar 2021 20:05:03
User entered 'Ondansetron'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:05:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Nausea'	Cassie Uminski (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '4'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:05:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4)	23 Mar 2021 20:11:50
User entered 'once (ONCE)'	Cassie Uminski (b) (4)	23 Mar 2021 20:05:03
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:05:03
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:05:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:05:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:03

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User entered empty.	System	23 Mar 2021 20:05:03



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User entered empty.	System	23 Mar 2021 20:05:03

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:14
User entered empty.	System	23 Mar 2021 20:05:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:44:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:44:32
Data point term sent to Coder Coding entries removed.	System Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:46:51 06 Apr 2021 19:46:08
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 20:06:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 20:06:41
Data point term sent to Coder User entered 'Ketorolac'	System Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:07 23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:05:39
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
Signature has been broken.	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 19:46:08
User entered 'ABDOMINAL Cramping' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 19:46:08
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Abdominal Pain'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '15'	(b) (4)	23 Mar 2021 20:05:39
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:05:39
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:11:18
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Mar 2021 20:11:18
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	23 Mar 2021 20:11:18
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:05:39
User entered 'once (ONCE)'	System	23 Mar 2021 20:05:39
	Cassie Uminski (b) (4)	23 Mar 2021 20:05:39
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:05:39
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:05:39
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '14 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '28 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:39



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User entered empty.	System	23 Mar 2021 20:05:39

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User entered empty.	System	23 Mar 2021 20:05:39

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:19
User entered empty.	System	23 Mar 2021 20:05:39

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 19:47:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 19:47:32
Data point term sent to Coder	System	06 Apr 2021 19:46:52
Coding entries removed.	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 19:46:33
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 20:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 20:07:42
Data point term sent to Coder	System	23 Mar 2021 20:07:09
User entered 'Acetaminophen'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:06:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
Signature has been broken.	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 19:46:33
User entered 'ABDOMINAL Cramping' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 19:46:33
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Abdominal Pain'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '1000'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:06:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:12:01
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Mar 2021 20:12:01
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	23 Mar 2021 20:12:01
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:06:18
User entered 'once (ONCE)'	System	23 Mar 2021 20:06:18
	Cassie Uminski (b) (4)	23 Mar 2021 20:06:18
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:06:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Oral (ORAL)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:06:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:06:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '28 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:06:18

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	Cassie Uminski (b) (4)	23 Mar 2021 20:06:18

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User entered empty.	System	23 Mar 2021 20:06:18

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User entered empty.	System	23 Mar 2021 20:06:18

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:22
User entered empty.	System	23 Mar 2021 20:06:18

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL, PRODUCTS YNOM: ESTROGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:02
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
Data point term sent to Coder	System	23 Mar 2021 20:07:09
User entered 'Estrogen'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Dysfunctional uterine bleeding'	Cassie Uminski (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'unk'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Unknown'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:12:10
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Mar 2021 20:12:10
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	23 Mar 2021 20:12:10
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:07:06
User entered 'once (ONCE)'	System	23 Mar 2021 20:07:06
	Cassie Uminski (b) (4)	23 Mar 2021 20:07:06
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:07:06
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:07:06
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:07:06
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '25 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:07:06

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User entered empty.	System	23 Mar 2021 20:07:06

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User entered empty.	System	23 Mar 2021 20:07:06

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:30
User entered empty.	System	23 Mar 2021 20:07:06



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:18:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:18:41
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
Data point term sent to Coder	System	23 Mar 2021 20:08:11
User entered 'Iron'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Dysfunctional Uterine Bleeding/Anemia'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'unk'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'unknown'	(b) (4)	23 Mar 2021 20:08:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:13:07
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Mar 2021 20:13:07
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	23 Mar 2021 20:13:07
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Mar 2021 20:08:11
User entered 'once (ONCE)'	System	23 Mar 2021 20:08:11
	Cassie Uminski (b) (4)	23 Mar 2021 20:08:11
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:08:11
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	Cassie Uminski (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '25 Dec 2020'	(b) (4)	23 Mar 2021 20:08:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:08:11

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User entered empty.	System	23 Mar 2021 20:08:11



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User entered empty.	System	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:42
User entered empty.	System	23 Mar 2021 20:08:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:43:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:43:30
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
Data point term sent to Coder	System	23 Mar 2021 20:09:13
User entered 'Packed red blood cells'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:09:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Dysfunctional Uterine Bleeding/Anemia'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'I'	(b) (4)	23 Mar 2021 20:09:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Other (OTHER)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Unit'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	23 Mar 2021 20:13:25
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Mar 2021 20:10:32
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Mar 2021 20:10:32
User entered 'once daily (QD)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:32
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Mar 2021 20:09:11
User entered 'once (ONCE)'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:09:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:09:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:09:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '25 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:09:11



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:09:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User entered empty.	System	23 Mar 2021 20:13:25
User entered 'I'	System	23 Mar 2021 20:10:32
User entered empty.	System	23 Mar 2021 20:09:11

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User entered empty.	System	23 Mar 2021 20:13:25
User entered 'I'	System	23 Mar 2021 20:10:32
User entered empty.	System	23 Mar 2021 20:09:11

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:35
User entered empty.	System	23 Mar 2021 20:13:25
User entered '804 (804)'	System	23 Mar 2021 20:10:32
User entered empty.	System	23 Mar 2021 20:09:11

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:43:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:43:30
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
Data point term sent to Coder	System	23 Mar 2021 20:10:14
User entered 'Packed red blood cells'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Dysfunctional Uterine Bleeding/Anemia'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '2'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Units'	Cassie Uminski (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	23 Mar 2021 20:13:34
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Mar 2021 20:10:24
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Mar 2021 20:10:24
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Mar 2021 20:10:03
User entered 'once (ONCE)'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:10:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:10:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4)	23 Mar 2021 20:10:24
User entered '25 Dec 2020'	Cassie Uminski (b) (4)	23 Mar 2021 20:10:03
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:10:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User entered empty.	System	23 Mar 2021 20:10:03

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User entered empty.	System	23 Mar 2021 20:10:03

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:45
User entered empty.	System	23 Mar 2021 20:10:03

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:48:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:48:06
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
Data point term sent to Coder	System	23 Mar 2021 20:22:39
User entered 'Cetazolin'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4)	23 Mar 2021 20:22:19
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Thrombophlebitis'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'I'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'g (g)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:22:19
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'four times daily (QID)'	Cassie Uminski (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:22:19
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered empty.	(b) (4)	23 Mar 2021 20:22:19
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '29 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered '29 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:22:19

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User entered '4'	System	23 Mar 2021 20:22:19

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User entered '1'	System	23 Mar 2021 20:22:19

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:47
User entered '804 (804)'	System	23 Mar 2021 20:22:19



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 20:25:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 20:25:43
Data point term sent to Coder	System	23 Mar 2021 20:24:47
User entered 'Ferrous sulfate'	Cassie Uminski (b) (4) (b) (4)	23 Mar 2021 20:24:05

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The corresponding AE 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)	07 Apr 2021 12:09:24
Query 'Per DM CLR: The corresponding AE 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 'Updated. ' (Site from DM).	Naqib Ahmad (b) (4)	06 Apr 2021 20:23:01
User opened query 'Per DM CLR: The corresponding AE 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)	05 Apr 2021 04:50:21
User signature succeeded.	Mary Beth Manning (b) (4)	23 Mar 2021 23:36:17
User entered 'Iron deficiency anemia'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered '325'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:35:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:35:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered '29 Dec 2020'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 23:36:17
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	23 Mar 2021 20:24:05
	(b) (4)	

**US3182025**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Mar 2021 20:24:05



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 20:24:05

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 20:24:05

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:47:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:47:10
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:03
Data point term sent to Coder	System	24 Mar 2021 14:31:07
User entered 'Cephalexin'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'Thrombophlebitis'	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '500'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	24 Mar 2021 14:30:25
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'twice daily (BID)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '29 Dec 2020'	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '0'	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		07 Apr 2021 12:11:38
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'updated.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:27:42
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:50:58
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:03
User entered '04 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:30:25



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	Cassie Uminski (b) (4)	24 Mar 2021 14:30:25

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User entered '2'	System	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User entered '1'	System	24 Mar 2021 14:30:25

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:54
User entered '804 (804)'	System	24 Mar 2021 14:30:25

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 12:24:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:24:26
Data point term sent to Coder	System	24 Mar 2021 14:32:08
User entered 'Hydromorphone'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:31:40
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'Pain secondary to D&C'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '0.5'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:31:40
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	24 Mar 2021 14:31:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'other (OTHER)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'Every 15 minutes x3'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	24 Mar 2021 14:31:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '07 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '07 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:31:40

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User entered empty.	System	24 Mar 2021 14:31:40

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User entered empty.	System	24 Mar 2021 14:31:40

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:53:57
User entered empty.	System	24 Mar 2021 14:31:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:44:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:44:38
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:03
Data point term sent to Coder	System	24 Mar 2021 14:33:10
User entered 'Ibuprofen'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:32:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'Pain secondary to D&C'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered '400'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'other (OTHER)'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'Every 6 hours as needed'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered '07 Jan 2021'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:22
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:32:22

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:32:22

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:32:22



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 09:05:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 09:05:50
Data point term sent to Coder	System	24 Mar 2021 14:33:09
User entered 'Promethazine'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'Nausea'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '12.5'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	24 Mar 2021 14:32:56
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'once daily (QD)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	24 Mar 2021 14:32:56
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered empty.	(b) (4)	24 Mar 2021 14:32:56
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '07 Jan 2021'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered '0'	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		07 Apr 2021 12:12:03
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Prophylaxis for nausea.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:40:56
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:51:31
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:03
User entered '07 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 14:32:56
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User entered '1'	System	24 Mar 2021 14:32:56



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User entered '1'	System	24 Mar 2021 14:32:56

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:03
User entered '804 (804)'	System	24 Mar 2021 14:32:56

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, PRODUCT: CONTRAST MEDIA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 12:32:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 12:32:45
User signature succeeded.	Mary Beth Manning (b) (4)	12 Apr 2021 13:01:07
Data point term sent to Coder	System	12 Apr 2021 12:45:28
User closed query 'CDM Coding : Per query response, please update the drug name as IV CONTRAST (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	System	12 Apr 2021 12:44:51
Query 'CDM Coding : Per query response, please update the drug name as IV CONTRAST (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' answered with 'updated' (Site from System).	Jennifer Gaston (b) (4)	12 Apr 2021 12:44:51
Data point term sent to Coder	System	12 Apr 2021 12:44:27
Signature has been broken.	Jennifer Gaston (b) (4)	12 Apr 2021 12:44:18
User entered 'TV CONTRAST (Unknown)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	12 Apr 2021 12:44:18
User opened query 'CDM Coding : Per query response, please update the drug name as IV CONTRAST (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	Coder Import (b) (4)	09 Apr 2021 11:40:34
Data point term sent to Coder	System	08 Apr 2021 18:41:36
User closed query 'CDM Coding : Please provide the specific trade name for the reported medication IV CONTRAST and update the response in the drug name field along with active ingredients. Thank you.' (Site from System).	System	08 Apr 2021 18:41:33
Query 'CDM Coding : Please provide the specific trade name for the reported medication IV CONTRAST and update the response in the drug name field along with active ingredients. Thank you.' answered with 'unknown' (Site from System).	Jennifer Gaston (b) (4)	08 Apr 2021 18:41:33

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2554 of 2755

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding : Please provide the specific trade name for the reported medication IV CONTRAST and update the response in the drug name field along with active ingredients. Thank you. ' (Site from System).	Coder Import (b) (4)	08 Apr 2021 07:22:35
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 16:05:59
Data point term sent to Coder	System	26 Mar 2021 15:17:44
User entered 'IV contrast'	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'For CT Scan'	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '100'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'mL (mL)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:17:37



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	26 Mar 2021 15:17:37
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '14 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '0'	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '14 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:17:37
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User entered empty.	System	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User entered empty.	System	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:55
User entered empty.	System	26 Mar 2021 15:17:37

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 15:19:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 15:19:36
Data point term sent to Coder	System	26 Mar 2021 15:18:46
User entered 'Odansetron'	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Nausea'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '4'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '14 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '14 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:23
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User entered empty.	System	26 Mar 2021 15:18:23

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User entered empty.	System	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:08
User entered empty.	System	26 Mar 2021 15:18:23

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:17:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:17:36
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 16:05:59
Data point term sent to Coder	System	26 Mar 2021 15:19:48
User entered 'Ketorolac'	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:18:52



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Abdominal Pain'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '15'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	26 Mar 2021 15:18:52
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '14 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '0'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '14 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	Cassie Uminski (b) (4)	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User entered empty.	System	26 Mar 2021 15:18:52

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User entered empty.	System	26 Mar 2021 15:18:52



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:04
User entered empty.	System	26 Mar 2021 15:18:52

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 15:20:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 15:20:25
Data point term sent to Coder	System	26 Mar 2021 15:19:48
User entered 'Acetaminophen'	Cassie Uminski (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	26 Mar 2021 15:19:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Abdominal Pain'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '1000'	Cassie Uminski (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:19:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:19:22



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:19:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Oral (ORAL)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	26 Mar 2021 15:19:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:43:57
Signature has been broken.	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 20:52:04
User entered '28 Dec 2020' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	06 Apr 2021 20:52:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:19:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and MH start/stop dates as appropriate. ' (Site from DM).		14 Apr 2021 01:53:36
User signature succeeded.	Mary Beth Manning (b) (4)	07 Apr 2021 15:43:57
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and MH start/stop dates as appropriate. ' answered with 'Updated.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:52:10
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:52:04
User entered '28 Dec 2020' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	06 Apr 2021 20:52:04
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and MH start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:18:40
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	26 Mar 2021 15:19:22
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User entered empty.	System	26 Mar 2021 15:19:22

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User entered empty.	System	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:12
User entered empty.	System	26 Mar 2021 15:19:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL, PRODUCTS YNOM: ESTROGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:02
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 16:05:59
Data point term sent to Coder	System	26 Mar 2021 15:20:50
User entered 'Estrogen'	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Dysfunctional Uterine Bleeding'	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'unk'	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Unknown'	(b) (4)	26 Mar 2021 15:20:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	26 Mar 2021 15:20:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	26 Mar 2021 15:20:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '0'	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40
	(b) (4)	



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:20:40
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	26 Mar 2021 15:20:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User entered empty.	System	26 Mar 2021 15:20:40

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User entered empty.	System	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:22
User entered empty.	System	26 Mar 2021 15:20:40

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:18:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:18:40
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 16:05:59
Data point term sent to Coder	System	26 Mar 2021 15:21:51
User entered 'Iron'	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:21:35

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Iron Deficiency Anemia'	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'unknown'	(b) (4)	26 Mar 2021 15:21:35
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Unknown'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:21:35

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	26 Mar 2021 15:21:35
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:21:35
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User entered empty.	System	26 Mar 2021 15:21:35

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User entered empty.	System	26 Mar 2021 15:21:35

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:20
User entered empty.	System	26 Mar 2021 15:21:35

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:58:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:58:59
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 16:05:59
Data point term sent to Coder System	System	26 Mar 2021 15:23:54
User entered 'Packed Red Blood Cells'	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:23:22



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Iron deficiency Anemia'	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'I'	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Unit'	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'Intravenous (INTRAVENOUS)'	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22



US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered empty.	(b) (4)	26 Mar 2021 15:23:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '0'	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22
	(b) (4)	

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered '24 Dec 2020'	Cassie Uminski (b) (4)	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'No (N)'	(b) (4)	26 Mar 2021 15:23:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:35:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User entered empty.	System	26 Mar 2021 15:23:22

US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User entered empty.	System	26 Mar 2021 15:23:22



US3182025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:35:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:54:26
User entered empty.	System	26 Mar 2021 15:23:22

US3182025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:35:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:47
DataPoint Verified.		14 Apr 2021 18:37:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
User closed query 'Please update to yes and add the procedure for dysfunctional bleeding or update the AE page as appropriate. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:00:17
Query 'Please update to yes and add the procedure for dysfunctional bleeding or update the AE page as appropriate. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:24:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:23:56
User opened query 'Please update to yes and add the procedure for dysfunctional bleeding or update the AE page as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 12:09:27
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Feb 2021 16:17:13

US3182025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:35:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:37:51
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
	(b) (4)	
User closed query 'Please clarify date of procedure. Hospital records page 94 has 07Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 18:15:55
Query 'Please clarify date of procedure. Hospital records page 94 has 07Jan2021. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4)	26 Mar 2021 15:02:26
	(b) (4)	
Signature has been broken.	Jennifer Gaston (b) (4)	26 Mar 2021 15:02:14
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	26 Mar 2021 15:02:14
	(b) (4)	
User opened query 'Please clarify date of procedure. Hospital records page 94 has 07Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 15:18:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered '15 Jan 2021'	Jennifer Gaston (b) (4)	27 Feb 2021 16:24:26
	(b) (4)	

US3182025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:35:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:37:51
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Dilation and Curettage'	Jennifer Gaston (b) (4)	27 Feb 2021 16:24:26
	(b) (4)	

US3182025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:35:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:37:51
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered 'Adverse Event (AE)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:24:26
	(b) (4)	

US3182025

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:35:54**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:37:51
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:01:52
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	27 Feb 2021 16:24:26
	(b) (4)	

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered	System	25 Mar 2021 15:58:01
'USA-US075-2021-MRNA-1273-P301000010'		

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:10
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:18
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:30
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Jennifer'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Gaston'	System	25 Mar 2021 15:58:01



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 12:38:09
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:18:55
	(b) (4)	
Un-reviewed for Safety.	System	22 Apr 2021 21:21:27
DataPoint Un-verified.	System	22 Apr 2021 21:21:27
Signature has been broken.	System	22 Apr 2021 21:21:27
User entered '3619 Park East Drive, Suite 300'	System	22 Apr 2021 21:21:27
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
	(b) (4)	

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:37
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'OH'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:41
Reviewed for Safety.		29 Mar 2021 13:02:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'US'	(b) (4) System	25 Mar 2021 15:59:24

**US3182025**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:35:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 21:21:27
User entered '2'	System	29 Mar 2021 13:02:14
User entered '1'	System	25 Mar 2021 15:59:24

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered	System	25 Mar 2021 15:58:01
'USA-US075-2021-MRNA-1273-P301000010'		

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:10
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:18
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:30
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Jennifer'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Gaston'	System	25 Mar 2021 15:58:01



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 12:38:09
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:18:55
	(b) (4)	
Un-reviewed for Safety.	System	22 Apr 2021 21:21:27
DataPoint Un-verified.	System	22 Apr 2021 21:21:27
Signature has been broken.	System	22 Apr 2021 21:21:27
User entered '3619 Park East Drive, Suite 300'	System	22 Apr 2021 21:21:27
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
	(b) (4)	

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:37
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'OH'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:41
Reviewed for Safety.		29 Mar 2021 13:02:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'US'	(b) (4) System	25 Mar 2021 15:59:24

**US3182025**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:35:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 21:21:27
User entered '2'	System	29 Mar 2021 13:02:14
User entered '1'	System	25 Mar 2021 15:59:24

**US3182025**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:35:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:39:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
User entered '25/Mar/2021 11:59'	System	25 Mar 2021 15:59:24

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:35:54

**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)	02 Apr 2021 18:39:02
Reviewed for Safety.		29 Mar 2021 13:02:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:24



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered	System	25 Mar 2021 15:58:01
'USA-US075-2021-MRNA-1273-P301000010'		

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:10
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:18
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:30
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Jennifer'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Gaston'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 12:38:09
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:18:55
	(b) (4)	
Un-reviewed for Safety.	System	22 Apr 2021 21:21:27
DataPoint Un-verified.	System	22 Apr 2021 21:21:27
Signature has been broken.	System	22 Apr 2021 21:21:27
User entered '3619 Park East Drive, Suite 300'	System	22 Apr 2021 21:21:27
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
	(b) (4)	

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:37
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'OH'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:41
Reviewed for Safety.		29 Mar 2021 13:02:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'US'	(b) (4) System	25 Mar 2021 15:59:24

**US3182025**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:35:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 21:21:27
User entered '2'	System	29 Mar 2021 13:02:14
User entered '1'	System	25 Mar 2021 15:59:24



**US3182025**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:35:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:39:13
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
	(b) (4)	
User entered '29/Mar/2021 08:02'	System	29 Mar 2021 13:02:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:35:54

**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)	22 Apr 2021 21:21:15
DataPoint Verified.		02 Apr 2021 18:39:13
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:47:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:02:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered	System	25 Mar 2021 15:58:01
'USA-US075-2021-MRNA-1273-P301000010'		

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:10
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:18
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Yes (Y)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:26
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:30
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'No (N)'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Jennifer'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'Gaston'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 12:38:09
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:18:55
	(b) (4)	
Un-reviewed for Safety.	System	22 Apr 2021 21:21:27
DataPoint Un-verified.	System	22 Apr 2021 21:21:27
Signature has been broken.	System	22 Apr 2021 21:21:27
User entered '3619 Park East Drive, Suite 300'	System	22 Apr 2021 21:21:27
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4)	15 Apr 2021 14:55:14
	(b) (4)	

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:37
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:59:07
User entered 'OH'	System	25 Mar 2021 15:58:01

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 21:21:15
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 19:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:03:26
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:55:14



US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:38:41
Reviewed for Safety.		29 Mar 2021 13:02:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:03
User entered 'US'	(b) (4) System	25 Mar 2021 15:59:24

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 21:21:27
User entered '2'	System	29 Mar 2021 13:02:14
User entered '1'	System	25 Mar 2021 15:59:24

**US3182025**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:35:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 12:38:13
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:18:55
	(b) (4)	
User entered '22/Apr/2021 17:21'	System	22 Apr 2021 21:21:27

US3182025

Folder: SAE USA-US075-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:35:54

**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)	28 Apr 2021 12:38:13
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:18:55
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 21:21:27