

US3032112 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:47:59

All time stamps listed in this document are displayed in GMT

US3032112

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

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[Participant ID](#)

US3032112

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

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US3032112

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3032112

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Nov 2020 16:29:22

Generated On: 09 Jun 2021 14:47:59

Date of Birth (MMM yyyy)	(b) (6)	1989
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 type="radio"/>
	Not Reported	<input checked="" type="radio"/>
	Unknown	<input type="radio"/>
Race (Check All That Apply)		
White		True
Black		False
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		False
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 16:58:31

Generated On: 09 Jun 2021 14:47:59

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

US3032112

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

US3032112

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

Condition	ALLERGY TO SULFA-HIVES
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

US3032112

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

Condition	ALLERGY TO LEVAQUIN-HIVES
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)	

US3032112

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

Condition	MAMMARY DUCT ECTASIA LEFT
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032112

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

Condition	GENITAL HERPES
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Dec 2020 20:07:12

Generated On: 09 Jun 2021 14:47:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	5 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	21:14 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 21:14
Height ( <i>xxx.x</i> )	167.6 cm
Weight ( <i>xxx.x</i> )	100.2 kg
BMI ( <i>xxx.x</i> )	35.67136 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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



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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Date of assessment (*dd MMM yyyy*) 5 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 28 Oct 2020 15:24:44

Generated On: 09 Jun 2021 14:47:59

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	5 AUG 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)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 16:58:32

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101478

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Oct 2020 13:46:40

Generated On: 09 Jun 2021 14:47:59

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Oct 2020 13:46:40

Generated On: 09 Jun 2021 14:47:59

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)	5 AUG 2020
Time of assessment (00:00-23:59)	18:41 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 18:41
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Oct 2020 13:46:40

Generated On: 09 Jun 2021 14:47:59

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)	5 AUG 2020
Time of assessment (00:00-23:59)	21:14 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 21:14
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3032112

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 28 Oct 2020 15:24:44

Generated On: 09 Jun 2021 14:47:59

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

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) 5 AUG 2020

What was the treatment time? (00:00-23:59) 20:44 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 20:44

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 AUG 2020

Collection time (00:00-23:59)

19:30 (24 HR)

Collection date and time (derived)

5 AUG 2020 19:30

US3032112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	19:25	5 AUG 2020 19:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**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

98.4 °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

05 AUG 2020 21:14

PC Open Date & Time

05 AUG 2020 21:04

PC Close Date & Time

05 AUG 2020 23:34



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**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):

PC Time Stamp	06 AUG 2020 02:49
PC Open Date & Time	06 AUG 2020 00:29
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

06 AUG 2020 13:15

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 23:33

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:53

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**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

98.7 °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

09 AUG 2020 23:17

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**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

98.6 °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

10 AUG 2020 13:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

11 AUG 2020 13:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**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

05 AUG 2020 21:15

PC Open Date & Time

05 AUG 2020 21:04

PC Close Date & Time

05 AUG 2020 23:34



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**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

06 AUG 2020 02:48

PC Open Date & Time

06 AUG 2020 00:29

PC Close Date & Time

06 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**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

06 AUG 2020 13:16

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**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

07 AUG 2020 23:32

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**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

08 AUG 2020 12:53

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**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

09 AUG 2020 23:18

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**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

10 AUG 2020 13:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**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

11 AUG 2020 13:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**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 ☐



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

No ☐

Yes ☒

PC Time stamp	05 AUG 2020 21:15
PC Open Date & Time	05 AUG 2020 21:04
PC Close Date & Time	05 AUG 2020 23:34

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**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 ☐

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 02:48
PC Open Date & Time	06 AUG 2020 00:29
PC Close Date & Time	06 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 13:16
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 23:33
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**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 ☒



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:52
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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 ☒

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 23:19
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

59 of 2127

EAB) (1725)

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 13:18
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**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

61 of 2127

EAB) (1725)

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 13:29
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3032112

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 13 AUG 2020 00:42

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59



US3032112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 14:47:59

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 00:42
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3032112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

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)	03 SEP 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 08:20
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

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)	03 SEP 2020
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 09:39
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3032112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

03 SEP 2020

---

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

---

US3032112

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	03 SEP 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)	

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 09:07 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 09:07

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

What was the frequency of the study treatment dosing? ONCE

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

US3032112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 SEP 2020

Collection time (00:00-23:59)

08:30 (24 HR)

Collection date and time (derived)

03 SEP 2020 08:30

US3032112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:35	03 SEP 2020 08:35
Nasopharyngeal Swab 2	No		

US3032112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:58:32

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**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

98.0 °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

03 SEP 2020 09:39

PC Open Date & Time

03 SEP 2020 09:27

PC Close Date & Time

03 SEP 2020 11:57

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	04 SEP 2020 00:39
PC Open Date & Time	03 SEP 2020 12:52
PC Close Date & Time	04 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 18:07

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**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

98.1 °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

05 SEP 2020 12:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 15:23

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 03:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 20:41

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**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

03 SEP 2020 09:40

PC Open Date & Time

03 SEP 2020 09:27

PC Close Date & Time

03 SEP 2020 11:57

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 00:40

PC Open Date & Time

03 SEP 2020 12:52

PC Close Date & Time

04 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**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

04 SEP 2020 18:08

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**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

05 SEP 2020 12:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**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

06 SEP 2020 15:23

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**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

07 SEP 2020 12:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**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

09 SEP 2020 03:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**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

09 SEP 2020 20:41

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**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 ☐

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 09:40
PC Open Date & Time	03 SEP 2020 09:27
PC Close Date & Time	03 SEP 2020 11:57

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**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 ☐

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 07:22
PC Open Date & Time	03 SEP 2020 12:52
PC Close Date & Time	04 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**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 ☒

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:08
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:49
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59



US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**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 ☒

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:23
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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 ☒

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:03
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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 ☒

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 03:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:41
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59



US3032112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:51

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Sep 2020 18:21:54

Generated On: 09 Jun 2021 14:47:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Sep 2020 18:21:54

Generated On: 09 Jun 2021 14:47:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:07 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 08:07
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3032112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Sep 2020 18:21:54

Generated On: 09 Jun 2021 14:47:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3032112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Sep 2020 18:21:54

Generated On: 09 Jun 2021 14:47:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	29 SEP 2020 08:35

US3032112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Sep 2020 18:21:54

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

05 OCT 2020 23:46:14

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 12 OCT 2020 07:08:31

Patient Cloud Open Date & Time 12 OCT 2020 00:01

Patient Cloud Close Date & Time 16 OCT 2020 23:59

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

19 OCT 2020 07:39:48

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

03 NOV 2020 07:58:34

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 11:19:50
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59



US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 22:15:43

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 23:12:58

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

27 NOV 2020 05:34:19

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

05 DEC 2020 02:24:37

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 02:01:51
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 22:31:57

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

25 DEC 2020 00:10:10

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 17:32:47

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 15:51:42

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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22 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

29 JAN 2021 00:33:38

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

05 FEB 2021 07:56:59

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 09:14:03
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 17:57:02
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 21:47:28

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 02:40:42

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

12 MAR 2021 00:13:07

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

28 MAR 2021 18:18:13

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

02 APR 2021 07:48:05

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

09 APR 2021 09:08:52

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

16 APR 2021 20:50:02

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

25 APR 2021 11:42:01

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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

30 APR 2021 00:06:29

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 SEP 2021 23:59
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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59
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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	04 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 FEB 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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="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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 APR 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 APR 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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 <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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 705

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2022 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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="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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

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[Patient Cloud Open Date & Time](#)

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02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2022 23:59

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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°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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**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 ☐

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59



US3032112

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

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="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"/>

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

US3032112

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:47:59

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 21:47:38

US3032112

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Oct 2020 15:24:44

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Oct 2020 15:24:44

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:10:59

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Dec 2020 19:46:57

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 18:06:05

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3032112

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:39:20

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Feb 2021 19:39:20

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:39:20

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

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) \_\_\_\_\_

US3032112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

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.*

US3032112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	16:05 (24 HR)
Collection date and time (derived)	8 MAR 2021 16:05

US3032112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032112

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3032112**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

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*

**US3032112**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3032112**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:47:59**

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

**US3032112**

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

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

**Generated On: 09 Jun 2021 14:47:59**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3032112

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

Form: Visit Date

Data signed: (b) (4) 30 Jan 2021 16:47:34

Generated On: 09 Jun 2021 14:47:59

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

Visit date (dd MMM yyyy)	22 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3032112

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

Form: Unblinding

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

Date of updated informed consent ( <i>dd MMM yyyy</i> )	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	



US3032112

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

09:19 (24 HR)

Collection date and time (derived)

22 JAN 2021 09:19

US3032112

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	09:26
Collection Date and Time (derived)	22 JAN 2021 09:26

US3032112

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 19:54:29

Generated On: 09 Jun 2021 14:47:59

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3032112

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:31

Generated On: 09 Jun 2021 14:47:59

AEID USA-US032-2021-MRNA-1273-P30  
1000007

Adverse event BILATERAL TALIPES  
EQUINOVIRUS OF FETUS

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) 11 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☒  
No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (v12.003 331 of 2127  
EAB) (1725)

US3032112

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:31

Generated On: 09 Jun 2021 14:47:59

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	True
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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3032112

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:17:31

Generated On: 09 Jun 2021 14:47:59

---

MEDICAL RECORDS HAVE BEEN RECEIVED AND REVIEWED. SUBJECT REPORTED PREGNANCY TO THE SITE ON 22JAN2021 WHILE AT HER PARTICIPATION DECISION VISIT. THE SUBJECT WAS 24 WEEKS. HER LMP IS 11AUG2020. ESTIMATED DUE DATE IS 18MAY2021. THE SUBJECT WAS NOTED TO HAVE RECEIVED PLACEBO. FURTHER VACCINATION WAS WITHHELD. AT THE TIME OF VISIT, 22JAN2021, SUBJECT STATED HER PREGNANCY WAS PROGRESSING WELL. WHILE REVIEWING MEDICAL RECORDS IT IS NOTED THAT THERE ARE SEVERAL CONGENITAL ABNORMALITIES NOTED. U/S AND A FOLLOW UP AT A HIGH RISK OBGYN SHOWS THICK NUCHAL FOLD MEASURING 7.8MM AND 9.4 MM AT FOLLOW UP. BILATERAL TALIPES EQUINOVIRUS, LEVORATION OF CARDIAC AXIS, AND QUESTIONABLE ABNORMAL PROFILE. PER RECORDS REVIEW THE SUBJECT IS AWARE OF ABNORMALITIES AS OF 31DEC2020 AND DID NOT REPORT TO THE SITE. WILL CONTINUE TO FOLLOW PREGNANCY PROGRESSION.

---

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)	

---

---

US3032112

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:17:31

Generated On: 09 Jun 2021 14:47:59

AEID	
Adverse event	GESTATIONAL DIABETES
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)	5 FEB 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)	28 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3032112

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:17:31

Generated On: 09 Jun 2021 14:47:59

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) _____ _____	



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 06 Apr 2021 15:33:10

Generated On: 09 Jun 2021 14:47:59

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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.

---

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	ACYCLOVIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENITAL HERPES
Dose per administration	400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:59

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	GLYBURIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GESTATIONAL DIABETES
Dose per administration	2.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:59

	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)		5 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	OXYTOCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PREGNANCY POST-PARTUM
Dose per administration	20/1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNITS/ML
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

	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)		28 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	CLINDAMYCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	900
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:59

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)	28 APR 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 APR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	LACTATED RINGERS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>

Indication	LABOR AND DELIVERY
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify

Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:59

	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)		28 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	TERBUTALINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	0.25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:59

	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)		28 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:59

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☐  
No ☒

Indication LABOR AND DELIVERY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:59

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 checked="" type="checkbox"/>
If route of administration is Other, specify	EPIDURAL
Start date (dd MMM yyyy)	28 APR 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

Name of Medication BUTORPHANOL

Prophylaxis Yes ☐  
No ☒

Indication LABOR AND DELIVERY

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 ☐  
Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

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)	28 APR 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	CARBOPROST
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	250
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:59

	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 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	LOPERAMIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	2
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		28 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		28 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	FENTANYL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LABOR AND DELIVERY
Dose per administration	50
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:47:59

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	EPIDURAL	
Start date (dd MMM yyyy)	28 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	METOCLOPRAMIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

	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"/>
<hr/>		
If route of administration is Other, specify _____		
<hr/>		
Start date ( <i>dd MMM yyyy</i> )		28 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		28 APR 2021
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	MISOPROSTOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LABOR AND DELIVERY
Dose per administration	800
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:47:59

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRAVAGINAL	
Start date (dd MMM yyyy)	28 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 APR 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"/>

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	OXYTOCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	30
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNITS
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

	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)		28 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	ALKA-SELTZER
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:47:59

	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 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	TRANEXAMIC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LABOR AND DELIVERY
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:47:59

	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)		28 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 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"/>

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

Name of Medication	NICOTINE
Prophylaxis	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Indication	SMOKING CESSATION
------------	-------------------

Dose per administration	21
-------------------------	----

Dose unit	mg <input checked="" type="radio"/>
	ug <input type="radio"/>
	mL <input type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input checked="" type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input checked="" type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

	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 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 APR 2021
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 type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

Name of Medication EPHEDRINE SULFATE

Prophylaxis Yes ☐  
No ☒

Indication LABOR AND DELIVERY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

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)	28 APR 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 APR 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"/>

US3032112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3032112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 10 Mar 2021 15:21:07

Generated On: 09 Jun 2021 14:47:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 DEC 2020	ULTRASOUND	Adverse Event	

US3032112

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:47:59

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 ☐



US3032112

Folder: SAE USA-US032-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 15:26:19

Generated On: 09 Jun 2021 14:47:59

SAEID	USA-US032-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input checked="" type="radio"/> No <input type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3032112

Folder: SAE USA-US032-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 15:26:19

Generated On: 09 Jun 2021 14:47:59

SAEID	USA-US032-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input checked="" type="radio"/> No <input type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/FEB/2021 13:41
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

US3032112

Folder: SAE USA-US032-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Apr 2021 15:26:19

Generated On: 09 Jun 2021 14:47:59

SAEID	USA-US032-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input checked="" type="radio"/> No <input type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/FEB/2021 20:43
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

US3032112

Folder: SAE USA-US032-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Apr 2021 15:26:19

Generated On: 09 Jun 2021 14:47:59

SAEID	USA-US032-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input checked="" type="radio"/> No <input type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/APR/2021 14:36
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

US3032112 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

**US3032112**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:47:59**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:28:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'US3032112'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:54:15

**US3032112**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:11:21

**US3032112**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:54:16



**US3032112**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[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 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:11:21

**US3032112**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'SCRN'	System	06 Aug 2020 13:11:21

US3032112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:54:16

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '30'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'YEARS'	System	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '30'	System	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Female (F)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

US3032112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	18 Nov 2020 14:45:07
User entered 'Not Reported (NOT REPORTED)'	(b) (4) Linden DeBoer (b) (4)	18 Nov 2020 14:45:07
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 13:21:23
	(b) (4)	



**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

US3032112

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23



**US3032112**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:47:59**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:21:23

US3032112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:47:59**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'Aug 2020'	System	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:47:59**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2020'	System	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:47:59**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Amendment 1 (1)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:47:54

US3032112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:59

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:47:59**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:47:59**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:47:54



US3032112

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:47:59**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:54:16

**US3032112**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:47:59**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'I'	System	06 Aug 2020 01:47:54

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:47:59

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:32:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:47:44

**US3032112**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 14:47:59**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:33:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:31:25

US3032112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 07:47:53
' (Site from DM). Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	14 Sep 2020 22:22:18
' answered with 'DATA ENTERED' (Site from DM). User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	30 Aug 2020 07:58:22
' (Site from DM). User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Abscess drainage, LLT: Breast abscess drainage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 17:27:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 17:27:46
Data point term sent to Coder	System	06 Aug 2020 13:32:54
User entered 'abscess drained in right breast'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:21

**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'un May 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:21

**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:21



**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:21

US3032112

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
User entered 'UN May 2020' reason for change: Data Entry Error	System	13 Aug 2020 23:24:53
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	13 Aug 2020 23:24:53
User entered 'un UNK 2020'	(b) (4)	
	System	06 Aug 2020 13:32:21
	Kelsey Kelley (b) (4)	06 Aug 2020 13:32:21
	(b) (4)	

**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:21

**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'May 2020'	System	06 Aug 2020 13:32:21

**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2020'	System	06 Aug 2020 13:32:21

**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'May 2020'	System	13 Aug 2020 23:24:53
User entered 'Jan 2020'	System	06 Aug 2020 13:32:21

**US3032112**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2020'	System	06 Aug 2020 13:32:21

US3032112

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'Per MM: Please confirm if HIVES occurred due to PENICILLIN ALLERGY?' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 10:37:03
Query 'Per MM: Please confirm if HIVES occurred due to PENICILLIN ALLERGY?' answered with 'Data corrected' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 22:29:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 22:25:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:25:45
Data point term sent to Coder	System	14 Sep 2020 22:25:16
Coding entries removed.	(b) (4), (b) (6)	14 Sep 2020 22:24:15
User entered 'PENICILLIN ALLERGY' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 22:24:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:56:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:56:34
User opened query 'Per MM: Please confirm if HIVES occurred due to PENICILLIN ALLERGY?' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:38:36
Data point term sent to Coder	System	06 Aug 2020 13:32:54
User entered 'penicillin-hives'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:38



**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'un UNK 1992'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:38

**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:38

**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:38

**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:38

**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:32:38

**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'Jan 1992'	System	06 Aug 2020 13:32:38

**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '1992'	System	06 Aug 2020 13:32:38

**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:32:38



**US3032112**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:32:38

US3032112

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.	(b) (4)	07 Apr 2021 21:38:13
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:00:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:00:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:33:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:33:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:33:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 15:33:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:54:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:54:04
Data point term sent to Coder	System	06 Aug 2020 13:33:55
User entered 'allergy to sulfa-hives'	Kelsey Kelley (b) (4)	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'un UNK 1992'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'Jan 1992'	System	06 Aug 2020 13:33:19



**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '1992'	System	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:33:19

**US3032112**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:33:19

US3032112

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.	(b) (4)	07 Apr 2021 21:38:13
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:00:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:00:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 14:08:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 14:08:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:51:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:51:02
Data point term sent to Coder	System	06 Aug 2020 13:33:55
User entered 'allergy to levaquin-hives'	Kelsey Kelley (b) (4)	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:37



**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'Jan 2010'	System	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2010'	System	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:33:37

**US3032112**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:33:37

US3032112

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Mammary duct ectasia, LLT: Mammary duct ectasia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Sep 2020 20:05:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 20:05:47
User closed query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral Breasts. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:39:50
Query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral Breasts. Update Med History eCRF as appropriate. ' answered with 'DATA CORRECTED' (Site from DM).		14 Sep 2020 22:28:22
Data point term sent to Coder	System	14 Sep 2020 22:28:18
Coding entries removed.	(b) (4), (b) (6)	14 Sep 2020 22:28:03
User entered 'MAMMARY DUCT ECTASIA LEFT reason for change: Data Entry Error		14 Sep 2020 22:28:03
User opened query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral Breasts. Update Med History eCRF as appropriate. ' (Site from DM).		30 Aug 2020 07:58:33
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Mammary duct ectasia, LLT: Mammary duct ectasia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:37:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 13:37:17
Data point term sent to Coder	System	06 Aug 2020 13:35:56
User entered 'mammary duct ectasia'	Kelsey Kelley (b) (4)	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:34:56



**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'Jan 2018'	System	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2018'	System	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:34:56

**US3032112**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:34:56

US3032112

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Breast infections, PT: Breast abscess, LLT: Breast abscess - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Sep 2020 23:40:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 23:40:58
Data point term sent to Coder	System	14 Sep 2020 22:24:15
User entered 'ABSESS RIGHT BREAST'	(b) (4), (b) (6)	14 Sep 2020 22:23:21



**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'UN May 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 22:23:21

**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 22:23:21

**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 22:23:21

**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'UN May 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 22:23:21

**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 22:23:21

**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'May 2020'	System	14 Sep 2020 22:23:21

**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2020'	System	14 Sep 2020 22:23:21

**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'May 2020'	System	14 Sep 2020 22:23:21



**US3032112**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2020'	System	14 Sep 2020 22:23:21

US3032112

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Genital herpes - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	25 Mar 2021 16:41:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:41:29
Data point term sent to Coder	System	25 Mar 2021 16:40:55
User entered 'genital herpes'	Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'un UNK 2014'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:38:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'Jan 2014'	System	25 Mar 2021 16:40:24



**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '2014'	System	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	25 Mar 2021 16:40:24

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:29:27

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 13:29:48
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	06 Aug 2020 13:29:48
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	06 Aug 2020 13:29:48
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 13:29:48
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	06 Aug 2020 13:29:27
User entered '6 Aug 2020'	Kelsey Kelley (b) (4)	06 Aug 2020 13:29:27
	(b) (4)	

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '21:14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:29:27

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '5 Aug 2020 21:14'	System	06 Aug 2020 13:29:48
User entered '6 Aug 2020 21:14'	System	06 Aug 2020 13:29:27

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '167.6' cm	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 13:29:27
DataPoint set to visible.	(b) (4) System	06 Aug 2020 01:47:54



US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '100.2' kg	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 13:29:27
DataPoint set to visible.	(b) (4) System	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
Amendment Manager: User entered '35.67136'	System	16 Sep 2020 23:44:53
User entered '35.7'	System	06 Aug 2020 13:29:27
DataPoint set to visible.	System	06 Aug 2020 01:47:54

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'kg/m2'	System	06 Aug 2020 13:29:27
DataPoint set to visible.	System	06 Aug 2020 01:47:54

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:21:19
User closed query 'Per CDM RQ: Please remove the unit of temperature.	(b) (4)	
Thanks ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:59:15
Query 'Per CDM RQ: Please remove the unit of temperature.	Linden DeBoer (b) (4)	07 Oct 2020 13:41:39
Thanks ' answered with 'data updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 13:41:28
User opened query 'Per CDM RQ: Please remove the unit of temperature.	(b) (4)	
Thanks ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 04:46:38
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for “Not done” and not left empty). Please update accordingly.	(b) (4), (b) (6)	07 Oct 2020 04:46:38
' (Site from DM).		
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for “Not done” and not left empty). Please update accordingly.	Linden DeBoer (b) (4)	06 Oct 2020 15:44:30
' answered with 'Data updated :Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for “Not done” and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM).	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
	(b) (4)	

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for "Not done" and not left empty). Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:13:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 13:29:27
	(b) (4)	

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:12
User closed query 'Per CDM: Please note that the temperature is marked as "ND" and the Route of measurement is not required. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 06:42:44
Query 'Per CDM: Please note that the temperature is marked as "ND" and the Route of measurement is not required. Review and update as appropriate. ' answered with 'route removed' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:47:47
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:47:21
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:47:21
User opened query 'Per CDM: Please note that the temperature is marked as "ND" and the Route of measurement is not required. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:58:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:58:33
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:29:27

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:29:27

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:21:19
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 04:49:24
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' answered with 'Data updated :Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	06 Oct 2020 15:44:34
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	06 Oct 2020 15:44:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	06 Oct 2020 15:44:24
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:14:05
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:58:33
User entered '76'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:29:27



**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'bpm'	System	06 Aug 2020 13:29:27

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:21:19
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User entered '15'	Kelsey Kelley (b) (4)	06 Aug 2020 13:29:27
	(b) (4)	

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'breaths/min'	System	06 Aug 2020 13:29:27

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:21:19
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User entered '116'	Kelsey Kelley (b) (4)	06 Aug 2020 13:29:27
	(b) (4)	

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'mmHg'	System	06 Aug 2020 13:29:27

US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.	(b) (4)	07 Apr 2021 21:35:08
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:21:19
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	06 Oct 2020 15:44:24
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 04:02:00
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per PI' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 17:42:50
	(b) (4)	
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:44:53
User entered '55'	Kelsey Kelley (b) (4)	06 Aug 2020 13:29:27
	(b) (4)	

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'mmHg'	System	06 Aug 2020 13:29:27

**US3032112**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16



US3032112

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16

**US3032112**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:47:59**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:36:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:05

US3032112

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:36:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
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)	07 Sep 2020 10:42:01
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 14:17:01
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	06 Aug 2020 13:24:35
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	06 Aug 2020 13:24:35
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:35
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	06 Aug 2020 13:24:05
User entered '6 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:05

US3032112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:47:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	(b) (4) System	06 Aug 2020 13:23:23
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:23
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	06 Aug 2020 13:23:18
User entered '6 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18

US3032112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:47:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18

**US3032112**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:47:59**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18

US3032112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:47:59

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18

**US3032112**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18



US3032112

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:47:59

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18

**US3032112**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18

**US3032112**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:47:59**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:18

**US3032112**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:49

US3032112

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	06 Aug 2020 13:23:55
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 13:23:55
User opened query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
User entered '6 Aug 2020'	System	06 Aug 2020 13:23:49
	Kelsey Kelley (b) (4)	06 Aug 2020 13:23:49
	(b) (4)	

**US3032112**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Urine (URINE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:49

**US3032112**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Negative (NEGATIVE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:49

US3032112

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User closed query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:02:12
Signature has been broken.	Linden DeBoer (b) (4)	23 Oct 2020 16:30:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	Linden DeBoer (b) (4)	23 Oct 2020 16:29:54
User signature succeeded.	(b) (4)	
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	23 Oct 2020 13:33:20
	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 13:23:49
	(b) (4)	



**US3032112**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:49

**US3032112**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:34:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:23:49

**US3032112**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	06 Aug 2020 13:23:49

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10



US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10



US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

**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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

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 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '0'	Kelsey Kelley (b) (4)	06 Aug 2020 13:22:10

US3032112

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:37:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:10



US3032112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:24

US3032112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	06 Aug 2020 13:22:34
User entered '5 Aug 2020' reason for change: Data Entry Error	System	06 Aug 2020 13:22:34
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	Kelsey Kelley (b) (4)	06 Aug 2020 13:22:34
User entered '6 Aug 2020'	(b) (4)	
	System	06 Aug 2020 13:22:24
	Kelsey Kelley (b) (4)	06 Aug 2020 13:22:24
	(b) (4)	

US3032112

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:22:24

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'VISIT1'	System	06 Aug 2020 13:22:24

US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 13:22:34
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	06 Aug 2020 13:22:24
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 00:44:13

US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:25:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:25:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 00:44:13
User entered '101478' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 00:44:13

US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 00:44:13

US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

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)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:58



US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

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)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:58

US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:58

US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:58

US3032112

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:24:58

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:40
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:24:37
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:49:01
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:48:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:48:57
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:02:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:58:33
User entered '167.6' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:40
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Oct 2020 13:48:57
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	09 Oct 2020 13:48:57
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User entered '100.2' kg	Kelsey Kelley (b) (4)	06 Aug 2020 13:26:49
	(b) (4)	

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:40
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:24:37
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:49:01
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:48:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:48:57
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:02:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:58:33
User entered '167.6' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:40
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Oct 2020 13:48:57
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	09 Oct 2020 13:48:57
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User entered '100.2' kg	Kelsey Kelley (b) (4)	06 Aug 2020 13:26:49
	(b) (4)	



US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '18:41'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '5 Aug 2020 18:41'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49



US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '76'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'bpm'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'breaths/min'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '116'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 04:02:20
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per pi' (Site from System).		17 Sep 2020 17:43:07
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:44:53
User entered '55'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	06 Aug 2020 13:26:49



US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:40
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:24:37
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:49:01
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:48:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:48:57
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:02:13
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:58:33
User entered '167.6' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:40
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Oct 2020 13:48:57
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Kelsey Kelley (b) (4)	09 Oct 2020 13:48:57
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User entered '100.2' kg	Kelsey Kelley (b) (4)	06 Aug 2020 13:26:49
	(b) (4)	

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
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)	13 Aug 2020 06:56:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:27:25
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).		06 Aug 2020 13:26:49
User entered '21:14'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '5 Aug 2020 21:14'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49



US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '67'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'bpm'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'breaths/min'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '106'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	06 Aug 2020 13:26:49



US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '71'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	06 Aug 2020 13:26:49

US3032112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:22

US3032112

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:22

US3032112

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:39:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User closed query 'Per CDM, re-query: Per CCGs, 'Was the pregnancy test performed?' is to be recorded as "No" at Visit 1 Day 1 when it is on the same day as Screening. This field should not remain empty. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 09:58:42
Query 'Per CDM, re-query: Per CCGs, 'Was the pregnancy test performed?' is to be recorded as "No" at Visit 1 Day 1 when it is on the same day as Screening. This field should not remain empty. Please update accordingly. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	27 Oct 2020 13:53:01
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	27 Oct 2020 13:52:56
User opened query 'Per CDM, re-query: Per CCGs, 'Was the pregnancy test performed?' is to be recorded as "No" at Visit 1 Day 1 when it is on the same day as Screening. This field should not remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:02:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:02:38
User closed query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:02:37
Query 'Data is required. Please complete.' answered with 'data removed per DM request' (Site from System).	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:40

US3032112

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

Was the pregnancy test performed?

Audit	User	Time (GMT)
Query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' answered with 'data removed per DM request' (Site from DM). User opened query 'Data is required. Please complete.' (Site from System). Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:36
	System	23 Oct 2020 12:55:31
	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:31
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	23 Oct 2020 12:55:31
User opened query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and Was FSH sample collected? should be marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Keith Vrbicky (b) (4) (b) (4)	23 Oct 2020 11:46:41 28 Sep 2020 16:58:33
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:02

US3032112

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	23 Oct 2020 12:55:31
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	23 Oct 2020 12:55:31
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	06 Aug 2020 13:30:13
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 13:30:13
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:13
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	06 Aug 2020 13:30:02
User entered '6 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:02

US3032112

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 12:55:31
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 12:55:31
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User entered 'Urine (URINE)'	Kelsey Kelley (b) (4)	06 Aug 2020 13:30:02
	(b) (4)	



US3032112

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	23 Oct 2020 12:55:31
	(b) (4)	
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	23 Oct 2020 12:55:31
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Kelsey Kelley (b) (4)	06 Aug 2020 13:30:02
	(b) (4)	

US3032112

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.	(b) (4)	07 Apr 2021 21:39:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User closed query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 09:58:44
Query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	27 Oct 2020 13:53:05
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	27 Oct 2020 13:52:56
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	27 Oct 2020 13:52:56
User opened query 'Per CDM: Per CCGs, "Was FSH sample collected?" question is to be answered and the field should not remain empty. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:02:51
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:58:33
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:02

US3032112

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:02

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:39:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:30:02

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered empty.	System	06 Aug 2020 13:30:02

US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
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 Aug 2020 01:48:19
User entered 'Yes (Y)' reason for change: Data Entry Error	System	06 Aug 2020 01:48:19
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	06 Aug 2020 01:48:19
User entered empty.	(b) (4)	
	System	06 Aug 2020 01:48:14
	Kelsey Kelley (b) (4)	06 Aug 2020 01:48:14
	(b) (4)	

US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:48:14

US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

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)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:48:14



US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 01:48:19
User entered empty.	System	06 Aug 2020 01:48:14

US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	06 Aug 2020 13:22:34
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 13:22:34
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	06 Aug 2020 13:22:24
User entered '5 Aug 2020'	Kelsey Kelley (b) (4)	06 Aug 2020 01:48:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '20:44'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:48:14

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:47:59**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '5 Aug 2020 20:44'	System	06 Aug 2020 01:48:14

US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:48:14

US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:15
User entered 'ONCE'	System	06 Aug 2020 01:48:19
User entered empty.	System	06 Aug 2020 01:48:14

US3032112

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 01:48:19
User entered empty.	System	06 Aug 2020 01:48:14

US3032112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:29



US3032112

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 13:35:34
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 13:35:34
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '6 Aug 2020'	System	06 Aug 2020 13:35:29
	Kelsey Kelley (b) (4)	06 Aug 2020 13:35:29
	(b) (4)	

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:47:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:40:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '19:30'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:29

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '5 Aug 2020 19:30'	System	06 Aug 2020 13:35:34
User entered '6 Aug 2020 19:30'	System	06 Aug 2020 13:35:29

US3032112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:47:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 13:35:54
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 13:35:54
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '6 Aug 2020'	System	06 Aug 2020 13:35:48
	Kelsey Kelley (b) (4)	06 Aug 2020 13:35:48
	(b) (4)	

US3032112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:48

US3032112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:48

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '19:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:48

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '5 Aug 2020 19:25'	System	06 Aug 2020 13:35:54
User entered '6 Aug 2020 19:25'	System	06 Aug 2020 13:35:48



US3032112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:48

US3032112

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:48

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:35:48

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered empty.	System	06 Aug 2020 13:35:48

US3032112

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:36:27

**US3032112**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	06 Aug 2020 13:36:27

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:13:52', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31de0541-6707-42d6-98f7-23548bb9680c'	System	06 Aug 2020 02:14:18
User entered 'Yes (Y)'	System	06 Aug 2020 02:14:18



US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:14:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31de0541-6707-42d6-98f7-23548bb9680c' User entered '98.4'	System	06 Aug 2020 02:14:18
	System	06 Aug 2020 02:14:18

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:14:08', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31de0541-6707-42d6-98f7-23548bb9680c'	System	06 Aug 2020 02:14:18
User entered 'No (N)'	System	06 Aug 2020 02:14:18

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:14:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31de0541-6707-42d6-98f7-23548bb9680c'	System	06 Aug 2020 02:14:18
User entered '05 Aug 2020 21:14'	System	06 Aug 2020 02:14:18

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Aug 2020 21:04'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Aug 2020 23:34'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:49:28', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a15bfc0-216c-405d-a97d-6eddcf951636'	System	06 Aug 2020 07:49:51
User entered 'Yes (Y)'	System	06 Aug 2020 07:49:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:49:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a15bfc0-216c-405d-a97d-6eddcf951636'	System	06 Aug 2020 07:49:51
User entered '98.8'	System	06 Aug 2020 07:49:51



US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:49:46', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a15bfc0-216c-405d-a97d-6eddcf951636'	System	06 Aug 2020 07:49:51
User entered 'No (N)'	System	06 Aug 2020 07:49:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:49:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a15bfc0-216c-405d-a97d-6eddcf951636'	System	06 Aug 2020 07:49:51
User entered '06 Aug 2020 02:49'	System	06 Aug 2020 07:49:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 00:29'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 2'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:15:32', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f394c16b-10d0-44f5-833a-8becb82f7af2'	System	06 Aug 2020 18:15:51
User entered 'Yes (Y)'	System	06 Aug 2020 18:15:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:15:37', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f394c16b-10d0-44f5-833a-8becb82f7af2'	System	06 Aug 2020 18:15:51
User entered '98.4'	System	06 Aug 2020 18:15:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:15:46', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f394c16b-10d0-44f5-833a-8becb82f7af2'	System	06 Aug 2020 18:15:51
User entered 'No (N)'	System	06 Aug 2020 18:15:51



US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:15:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f394c16b-10d0-44f5-833a-8becb82f7af2'	System	06 Aug 2020 18:15:51
User entered '06 Aug 2020 13:15'	System	06 Aug 2020 18:15:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 3'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:37', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '11a49fe6-6f66-4f65-ab70-804137d23fb0'	System	08 Aug 2020 04:33:51
User entered 'Yes (Y)'	System	08 Aug 2020 04:33:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '11a49fe6-6f66-4f65-ab70-804137d23fb0'	System	08 Aug 2020 04:33:51
User entered '98.8'	System	08 Aug 2020 04:33:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:45', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '11a49fe6-6f66-4f65-ab70-804137d23fb0'	System	08 Aug 2020 04:33:51
User entered 'No (N)'	System	08 Aug 2020 04:33:51

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '11a49fe6-6f66-4f65-ab70-804137d23fb0'	System	08 Aug 2020 04:33:51
User entered '07 Aug 2020 23:33'	System	08 Aug 2020 04:33:51



US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 4'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c7954234-9d4e-48d3-925d-eebdb0003408'	System	08 Aug 2020 17:53:28
User entered 'Yes (Y)'	System	08 Aug 2020 17:53:28

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:20', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c7954234-9d4e-48d3-925d-eebdb0003408'	System	08 Aug 2020 17:53:28
User entered '98.5'	System	08 Aug 2020 17:53:28

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:23', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c7954234-9d4e-48d3-925d-eebdb0003408'	System	08 Aug 2020 17:53:28
User entered 'No (N)'	System	08 Aug 2020 17:53:28

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:24', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c7954234-9d4e-48d3-925d-eebdb0003408'	System	08 Aug 2020 17:53:28
User entered '08 Aug 2020 12:53'	System	08 Aug 2020 17:53:28

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 01:48:14



US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 5'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:17:45', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7f9411b8-1d33-4341-b812-8b3b371b90da'	System	10 Aug 2020 04:18:04
User entered 'Yes (Y)'	System	10 Aug 2020 04:18:04

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:17:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7f9411b8-1d33-4341-b812-8b3b371b90da'	System	10 Aug 2020 04:18:04
User entered '98.7'	System	10 Aug 2020 04:18:04

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:17:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7f9411b8-1d33-4341-b812-8b3b371b90da'	System	10 Aug 2020 04:18:04
User entered 'No (N)'	System	10 Aug 2020 04:18:04

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:17:58', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7f9411b8-1d33-4341-b812-8b3b371b90da'	System	10 Aug 2020 04:18:04
User entered '09 Aug 2020 23:17'	System	10 Aug 2020 04:18:04

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 01:48:14



US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 6'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b8622d60-71a2-4d7e-80e9-60328122a103'	System	10 Aug 2020 18:18:52
User entered 'Yes (Y)'	System	10 Aug 2020 18:18:52

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b8622d60-71a2-4d7e-80e9-60328122a103'	System	10 Aug 2020 18:18:52
User entered '98.6'	System	10 Aug 2020 18:18:52

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:46', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b8622d60-71a2-4d7e-80e9-60328122a103'	System	10 Aug 2020 18:18:52
User entered 'No (N)'	System	10 Aug 2020 18:18:52

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b8622d60-71a2-4d7e-80e9-60328122a103'	System	10 Aug 2020 18:18:52
User entered '10 Aug 2020 13:18'	System	10 Aug 2020 18:18:52

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 7'	System	06 Aug 2020 01:48:14



US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:27:52', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '41f6c619-d3a5-4400-8e06-9ee042247fa1'	System	11 Aug 2020 18:28:09
User entered 'Yes (Y)'	System	11 Aug 2020 18:28:09

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:27:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '41f6c619-d3a5-4400-8e06-9ee042247fa1'	System	11 Aug 2020 18:28:09
User entered '97.7'	System	11 Aug 2020 18:28:09

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:27:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '41f6c619-d3a5-4400-8e06-9ee042247fa1'	System	11 Aug 2020 18:28:09
User entered 'No (N)'	System	11 Aug 2020 18:28:09

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '41f6c619-d3a5-4400-8e06-9ee042247fa1'	System	11 Aug 2020 18:28:09
User entered '11 Aug 2020 13:28'	System	11 Aug 2020 18:28:09

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:14:18', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '06003947-1879-4f20-8783-b943d5e8836b'	System	06 Aug 2020 02:15:09
User entered 'None (1)'	System	06 Aug 2020 02:15:09



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:14:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '06003947-1879-4f20-8783-b943d5e8836b'	System	06 Aug 2020 02:15:09
User entered 'No (N)'	System	06 Aug 2020 02:15:09

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '06003947-1879-4f20-8783-b943d5e8836b'	System	06 Aug 2020 02:15:09
User entered 'No (N)'	System	06 Aug 2020 02:15:09

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '06003947-1879-4f20-8783-b943d5e8836b'	System	06 Aug 2020 02:15:09
User entered 'None (1)'	System	06 Aug 2020 02:15:09

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:07', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '06003947-1879-4f20-8783-b943d5e8836b'	System	06 Aug 2020 02:15:09
User entered '05 Aug 2020 21:15'	System	06 Aug 2020 02:15:09

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Aug 2020 21:04'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Aug 2020 23:34'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:33', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0dd8f34e-a670-4753-bcf5-172a0812a776'	System	06 Aug 2020 07:48:47
User entered 'None (1)'	System	06 Aug 2020 07:48:47



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:36', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0dd8f34e-a670-4753-bcf5-172a0812a776'	System	06 Aug 2020 07:48:47
User entered 'No (N)'	System	06 Aug 2020 07:48:47

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0dd8f34e-a670-4753-bcf5-172a0812a776'	System	06 Aug 2020 07:48:47
User entered 'No (N)'	System	06 Aug 2020 07:48:47

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0dd8f34e-a670-4753-bcf5-172a0812a776'	System	06 Aug 2020 07:48:47
User entered 'None (1)'	System	06 Aug 2020 07:48:47

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0dd8f34e-a670-4753-bcf5-172a0812a776'	System	06 Aug 2020 07:48:47
User entered '06 Aug 2020 02:48'	System	06 Aug 2020 07:48:47

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 00:29'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 2'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435834ce-bbcf-4ffb-94b3-9c71bba468ab'	System	06 Aug 2020 18:16:40
User entered 'None (1)'	System	06 Aug 2020 18:16:40



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:29', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435834ce-bbcf-4ffb-94b3-9c71bba468ab'	System	06 Aug 2020 18:16:40
User entered 'No (N)'	System	06 Aug 2020 18:16:40

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:31', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435834ce-bbcf-4ffb-94b3-9c71bba468ab'	System	06 Aug 2020 18:16:40
User entered 'No (N)'	System	06 Aug 2020 18:16:40

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:32', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435834ce-bbcf-4ffb-94b3-9c71bba468ab'	System	06 Aug 2020 18:16:40
User entered 'None (1)'	System	06 Aug 2020 18:16:40

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435834ce-bbcf-4ffb-94b3-9c71bba468ab'	System	06 Aug 2020 18:16:40
User entered '06 Aug 2020 13:16'	System	06 Aug 2020 18:16:40

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 3'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:32:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435c3bd7-cd55-4803-a87b-f8a41d0c6696'	System	08 Aug 2020 04:32:57
User entered 'None (1)'	System	08 Aug 2020 04:32:57



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:32:45', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435c3bd7-cd55-4803-a87b-f8a41d0c6696'	System	08 Aug 2020 04:32:57
User entered 'No (N)'	System	08 Aug 2020 04:32:57

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:32:47', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435c3bd7-cd55-4803-a87b-f8a41d0c6696'	System	08 Aug 2020 04:32:57
User entered 'No (N)'	System	08 Aug 2020 04:32:57

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:32:49', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435c3bd7-cd55-4803-a87b-f8a41d0c6696'	System	08 Aug 2020 04:32:57
User entered 'None (1)'	System	08 Aug 2020 04:32:57

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:32:52', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '435c3bd7-cd55-4803-a87b-f8a41d0c6696'	System	08 Aug 2020 04:32:57
User entered '07 Aug 2020 23:32'	System	08 Aug 2020 04:32:57

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 4'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd4f35dfe-9c8f-4862-9b71-3f54bf52467f'	System	08 Aug 2020 17:53:11
User entered 'None (1)'	System	08 Aug 2020 17:53:11



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd4f35dfe-9c8f-4862-9b71-3f54bf52467f'	System	08 Aug 2020 17:53:11
User entered 'No (N)'	System	08 Aug 2020 17:53:11

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:03', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd4f35dfe-9c8f-4862-9b71-3f54bf52467f'	System	08 Aug 2020 17:53:11
User entered 'No (N)'	System	08 Aug 2020 17:53:11

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd4f35dfe-9c8f-4862-9b71-3f54bf52467f'	System	08 Aug 2020 17:53:11
User entered 'None (1)'	System	08 Aug 2020 17:53:11

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:53:06', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd4f35dfe-9c8f-4862-9b71-3f54bf52467f'	System	08 Aug 2020 17:53:11
User entered '08 Aug 2020 12:53'	System	08 Aug 2020 17:53:11

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 5'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:02', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd17facdb-4240-4660-8c87-7386266d363f'	System	10 Aug 2020 04:18:20
User entered 'None (1)'	System	10 Aug 2020 04:18:20



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd17facdb-4240-4660-8c87-7386266d363f'	System	10 Aug 2020 04:18:20
User entered 'No (N)'	System	10 Aug 2020 04:18:20

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:07', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd17facdb-4240-4660-8c87-7386266d363f'	System	10 Aug 2020 04:18:20
User entered 'No (N)'	System	10 Aug 2020 04:18:20

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:09', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd17facdb-4240-4660-8c87-7386266d363f'	System	10 Aug 2020 04:18:20
User entered 'None (1)'	System	10 Aug 2020 04:18:20

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:14', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd17facdb-4240-4660-8c87-7386266d363f'	System	10 Aug 2020 04:18:20
User entered '09 Aug 2020 23:18'	System	10 Aug 2020 04:18:20

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 6'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:08', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '8095623b-1c80-41ba-afe5-4af26e659cb2'	System	10 Aug 2020 18:18:23
User entered 'None (1)'	System	10 Aug 2020 18:18:23



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:10', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '8095623b-1c80-41ba-afe5-4af26e659cb2'	System	10 Aug 2020 18:18:23
User entered 'No (N)'	System	10 Aug 2020 18:18:23

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '8095623b-1c80-41ba-afe5-4af26e659cb2'	System	10 Aug 2020 18:18:23
User entered 'No (N)'	System	10 Aug 2020 18:18:23

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:13', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '8095623b-1c80-41ba-afe5-4af26e659cb2'	System	10 Aug 2020 18:18:23
User entered 'None (1)'	System	10 Aug 2020 18:18:23

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:17', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '8095623b-1c80-41ba-afe5-4af26e659cb2'	System	10 Aug 2020 18:18:23
User entered '10 Aug 2020 13:18'	System	10 Aug 2020 18:18:23

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 7'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:09', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '160fafd4-1b53-4f1a-bb6f-005403d94d6b'	System	11 Aug 2020 18:28:27
User entered 'None (1)'	System	11 Aug 2020 18:28:27



US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:10', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '160fafd4-1b53-4f1a-bb6f-005403d94d6b'	System	11 Aug 2020 18:28:27
User entered 'No (N)'	System	11 Aug 2020 18:28:27

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:15', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '160fafd4-1b53-4f1a-bb6f-005403d94d6b'	System	11 Aug 2020 18:28:27
User entered 'No (N)'	System	11 Aug 2020 18:28:27

US3032112

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:17', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '160fafd4-1b53-4f1a-bb6f-005403d94d6b'	System	11 Aug 2020 18:28:27
User entered 'None (1)'	System	11 Aug 2020 18:28:27

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:20', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '160fafd4-1b53-4f1a-bb6f-005403d94d6b'	System	11 Aug 2020 18:28:27
User entered '11 Aug 2020 13:28'	System	11 Aug 2020 18:28:27

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered 'None (0)'	System	06 Aug 2020 02:15:40



**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:14', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered 'None (0)'	System	06 Aug 2020 02:15:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:16', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered 'None (0)'	System	06 Aug 2020 02:15:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:25', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered 'None (0)'	System	06 Aug 2020 02:15:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:27', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered 'None (0)'	System	06 Aug 2020 02:15:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:30', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered 'None (0)'	System	06 Aug 2020 02:15:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered 'Yes (Y)'	System	06 Aug 2020 02:15:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-05T21:15:37', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0efc6114-2fc7-4277-b39c-47acd2d05c86'	System	06 Aug 2020 02:15:40
User entered '05 Aug 2020 21:15'	System	06 Aug 2020 02:15:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Aug 2020 21:04'	System	06 Aug 2020 01:48:14



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Aug 2020 23:34'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:09', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered 'None (0)'	System	06 Aug 2020 07:48:29

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:11', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered 'None (0)'	System	06 Aug 2020 07:48:29

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:13', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered 'None (0)'	System	06 Aug 2020 07:48:29

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:15', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered 'None (0)'	System	06 Aug 2020 07:48:29

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:17', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered 'None (0)'	System	06 Aug 2020 07:48:29

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:19', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered 'None (0)'	System	06 Aug 2020 07:48:29



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:23', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered 'No (N)'	System	06 Aug 2020 07:48:29

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T02:48:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '793c430c-8f4a-41dc-918c-0c4f8519fec4'	System	06 Aug 2020 07:48:29
User entered '06 Aug 2020 02:48'	System	06 Aug 2020 07:48:29

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 00:29'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 2'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:39', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24'	System	06 Aug 2020 18:16:54
User entered 'None (0)'	System	06 Aug 2020 18:16:54

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24'	System	06 Aug 2020 18:16:54
User entered 'None (0)'	System	06 Aug 2020 18:16:54

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24'	System	06 Aug 2020 18:16:54
User entered 'None (0)'	System	06 Aug 2020 18:16:54



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24' User entered 'None (0)'	System	06 Aug 2020 18:16:54
	System	06 Aug 2020 18:16:54

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:46', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24'	System	06 Aug 2020 18:16:54
User entered 'None (0)'	System	06 Aug 2020 18:16:54

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:47', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24'	System	06 Aug 2020 18:16:54
User entered 'None (0)'	System	06 Aug 2020 18:16:54

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:49', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24'	System	06 Aug 2020 18:16:54
User entered 'No (N)'	System	06 Aug 2020 18:16:54

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-06T13:16:51', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '60eba3b5-180e-4ea7-88eb-231aad939c24'	System	06 Aug 2020 18:16:54
User entered '06 Aug 2020 13:16'	System	06 Aug 2020 18:16:54

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 3'	System	06 Aug 2020 01:48:14



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:32:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered 'None (0)'	System	08 Aug 2020 04:33:35

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:32:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered 'None (0)'	System	08 Aug 2020 04:33:35

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered 'None (0)'	System	08 Aug 2020 04:33:35

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:05', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered 'None (0)'	System	08 Aug 2020 04:33:35

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered 'None (0)'	System	08 Aug 2020 04:33:35

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:14', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered 'None (0)'	System	08 Aug 2020 04:33:35

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:20', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered 'No (N)'	System	08 Aug 2020 04:33:35

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-07T23:33:30', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9e6af4c6-ae33-4307-a8c4-c7f7009350c5'	System	08 Aug 2020 04:33:35
User entered '07 Aug 2020 23:33'	System	08 Aug 2020 04:33:35



**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 4'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:43', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered 'None (0)'	System	08 Aug 2020 17:53:00

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered 'None (0)'	System	08 Aug 2020 17:53:00

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:47', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered 'None (0)'	System	08 Aug 2020 17:53:00

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered 'None (0)'	System	08 Aug 2020 17:53:00

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:50', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered 'None (0)'	System	08 Aug 2020 17:53:00



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:51', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered 'None (0)'	System	08 Aug 2020 17:53:00

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered 'No (N)'	System	08 Aug 2020 17:53:00

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-08T12:52:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '394be381-84a4-4a68-b0ca-022d8718a94b'	System	08 Aug 2020 17:53:00
User entered '08 Aug 2020 12:52'	System	08 Aug 2020 17:53:00

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 5'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered 'None (0)'	System	10 Aug 2020 04:19:12

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:38', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered 'None (0)'	System	10 Aug 2020 04:19:12



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:39', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered 'None (0)'	System	10 Aug 2020 04:19:12

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered 'None (0)'	System	10 Aug 2020 04:19:12

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:45', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered 'None (0)'	System	10 Aug 2020 04:19:12

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:47', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered 'None (0)'	System	10 Aug 2020 04:19:12

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:18:57', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered 'No (N)'	System	10 Aug 2020 04:19:12

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-09T23:19:03', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'a7d9e640-b1ff-4350-b58d-dbdda1034b86'	System	10 Aug 2020 04:19:12
User entered '09 Aug 2020 23:19'	System	10 Aug 2020 04:19:12

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 01:48:14



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 6'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:21', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered 'None (0)'	System	10 Aug 2020 18:18:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:22', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered 'None (0)'	System	10 Aug 2020 18:18:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:24', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered 'None (0)'	System	10 Aug 2020 18:18:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:25', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered 'None (0)'	System	10 Aug 2020 18:18:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered 'None (0)'	System	10 Aug 2020 18:18:40

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:29', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered 'None (0)'	System	10 Aug 2020 18:18:40

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:31', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered 'No (N)'	System	10 Aug 2020 18:18:40



**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-10T13:18:34', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2d7f0a0c-8690-4321-816d-d80a3a545558'	System	10 Aug 2020 18:18:40
User entered '10 Aug 2020 13:18'	System	10 Aug 2020 18:18:40

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 7'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered 'No interference with activity (1)'	System	11 Aug 2020 18:29:11

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:47', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered 'None (0)'	System	11 Aug 2020 18:29:11

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:49', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered 'None (0)'	System	11 Aug 2020 18:29:11

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:54', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered 'None (0)'	System	11 Aug 2020 18:29:11



US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:57', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered 'None (0)'	System	11 Aug 2020 18:29:11

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:28:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered 'None (0)'	System	11 Aug 2020 18:29:11

US3032112

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:29:02', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered 'No (N)'	System	11 Aug 2020 18:29:11

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-11T13:29:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'c80ed495-d0d5-49ca-8e7e-23046809b6b2'	System	11 Aug 2020 18:29:11
User entered '11 Aug 2020 13:29'	System	11 Aug 2020 18:29:11

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 01:48:14

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 01:48:14

US3032112

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	11 Aug 2020 18:29:11
User entered 'Day 8'	System	11 Aug 2020 18:29:11

US3032112

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 14:47:59

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-13T00:42:07', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b70c00a0-cd94-4a0f-828b-36db6898e961'	System	13 Aug 2020 05:42:18
User entered 'None (0)'	System	13 Aug 2020 05:42:18



**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-13T00:42:13', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b70c00a0-cd94-4a0f-828b-36db6898e961'	System	13 Aug 2020 05:42:18
User entered '13 Aug 2020 00:42'	System	13 Aug 2020 05:42:18

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:29:11

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:29:11

US3032112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	11 Aug 2020 18:29:11
User entered 'Day 8'	System	11 Aug 2020 18:29:11

US3032112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-13T00:42:17', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '337ea697-0e85-488c-aec8-def1280aa98d'	System	13 Aug 2020 05:42:25
User entered 'No (N)'	System	13 Aug 2020 05:42:25

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-08-13T00:42:19', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '337ea697-0e85-488c-aec8-def1280aa98d'	System	13 Aug 2020 05:42:25
User entered '13 Aug 2020 00:42'	System	13 Aug 2020 05:42:25

US3032112

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:29:11

**US3032112**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:29:11



US3032112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:40:52

US3032112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	18 Aug 2020 18:41:12
Query 'Safety Call Day 8 'Date of Contact or Contact System Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).		18 Aug 2020 18:41:12
User entered '14 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	18 Aug 2020 18:41:12
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	18 Aug 2020 18:40:52
User entered '18 Aug 2020'	System	18 Aug 2020 18:40:52
	Kelsey Kelley (b) (4)	18 Aug 2020 18:40:52
	(b) (4)	

US3032112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:40:52

US3032112

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:40:52

US3032112

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 18:41:16

**US3032112**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	18 Aug 2020 18:41:16

**US3032112**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:15:04

US3032112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	03 Sep 2020 14:15:43
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	03 Sep 2020 14:15:43
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:15:43
User entered '24 Aug 2020' reason for change: Data Entry Error		03 Sep 2020 14:15:22
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Sep 2020 14:15:04
User entered '25 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 14:15:04



US3032112

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:15:04

**US3032112**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:41:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:15:04

US3032112

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:42:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:15:50

**US3032112**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	03 Sep 2020 14:15:50

US3032112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:42:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:16:19

**US3032112**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:42:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:16:19

US3032112

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:42:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:16:19

**US3032112**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:42:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:16:19



US3032112

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:44:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:16:39

**US3032112**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	03 Sep 2020 14:16:39

US3032112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:44:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:01

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:44:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:01

US3032112

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:44:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:01

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'VISIT2'	System	03 Sep 2020 14:17:01

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Pre-Dose (PREDOSE)'		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49



US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '08:20'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '03 Sep 2020 08:20'	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '74'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'bpm'	System	03 Sep 2020 14:17:49



US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '14'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'breaths/min'	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '94'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '64'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Post-Dose (POSTDOSE)'		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
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	03 Sep 2020 15:18:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:18:49
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:17:49
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 14:17:49



US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 15:18:49
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 14:17:49

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:47:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '09:39' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:18:49
		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '03 Sep 2020 09:39'	System	03 Sep 2020 15:18:49
User entered empty.	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '36.7' C reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:18:49
		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:18:49
		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '58' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:18:49
		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'bpm'	System	03 Sep 2020 15:18:49
User entered empty.	System	03 Sep 2020 14:17:49



US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '15' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:18:49
		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'breaths/min'	System	03 Sep 2020 15:18:49
User entered empty.	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '110' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 15:18:49
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	03 Sep 2020 15:18:49
User entered empty.	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '77' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 15:18:49
User entered empty.		03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	03 Sep 2020 15:18:49
User entered empty.	System	03 Sep 2020 14:17:49

US3032112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:04

US3032112

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:04



US3032112

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:18

US3032112

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:18

US3032112

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:18

US3032112

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:18

US3032112

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:18

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:18

US3032112

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:47:59

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:46:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:18

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered empty.	System	03 Sep 2020 14:18:18



US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

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)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:47

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:47:59**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '09:07'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '03 Sep 2020 09:07'	System	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:18:47



US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:12
User entered 'ONCE'	System	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 14:18:47

US3032112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:04

US3032112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:04

US3032112

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '08:30'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:04

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '03 Sep 2020 08:30'	System	03 Sep 2020 14:19:04

US3032112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:47:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:20

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		03 Sep 2020 14:19:20



US3032112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:20

US3032112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered '08:35'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:20

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '03 Sep 2020 08:35'	System	03 Sep 2020 14:19:20

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		03 Sep 2020 14:19:20

US3032112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:20

US3032112

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:46
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:20

**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered empty.	System	03 Sep 2020 14:19:20

US3032112

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:47:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:19:23



**US3032112**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	03 Sep 2020 14:19:23

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:39:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ac590587-aadf-4a2f-b60d-4110061acbeb'	System	03 Sep 2020 14:40:03
User entered 'Yes (Y)'	System	03 Sep 2020 14:40:03

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:39:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ac590587-aadf-4a2f-b60d-4110061acbeb'	System	03 Sep 2020 14:40:03
User entered '98.0'	System	03 Sep 2020 14:40:03

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:39:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ac590587-aadf-4a2f-b60d-4110061acbeb'	System	03 Sep 2020 14:40:03
User entered 'No (N)'	System	03 Sep 2020 14:40:03

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:39:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ac590587-aadf-4a2f-b60d-4110061acbeb'	System	03 Sep 2020 14:40:03
User entered '03 Sep 2020 09:39'	System	03 Sep 2020 14:40:03

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 09:27'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 11:57'	System	03 Sep 2020 14:18:47



US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:32:06', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7bb20d40-bb8b-4131-89ce-ad796f072a6f'	System	04 Sep 2020 05:39:50
User entered 'Yes (Y)'	System	04 Sep 2020 05:39:50

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:39:41', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7bb20d40-bb8b-4131-89ce-ad796f072a6f' User entered '98.7'	System	04 Sep 2020 05:39:50
	System	04 Sep 2020 05:39:50

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:39:43', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7bb20d40-bb8b-4131-89ce-ad796f072a6f'	System	04 Sep 2020 05:39:50
User entered 'No (N)'	System	04 Sep 2020 05:39:50

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:39:46', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7bb20d40-bb8b-4131-89ce-ad796f072a6f'	System	04 Sep 2020 05:39:50
User entered '04 Sep 2020 00:39'	System	04 Sep 2020 05:39:50

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 12:52'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 2'	System	03 Sep 2020 14:18:47



US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:07:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae909d07-5f75-47b9-a30c-e9dff319111d'	System	04 Sep 2020 23:08:03
User entered 'Yes (Y)'	System	04 Sep 2020 23:08:03

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:07:46', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae909d07-5f75-47b9-a30c-e9dff319111d' User entered '97.5'	System	04 Sep 2020 23:08:03
	System	04 Sep 2020 23:08:03

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:07:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae909d07-5f75-47b9-a30c-e9dff319111d'	System	04 Sep 2020 23:08:03
User entered 'No (N)'	System	04 Sep 2020 23:08:03

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:07:55', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae909d07-5f75-47b9-a30c-e9dff319111d'	System	04 Sep 2020 23:08:03
User entered '04 Sep 2020 18:07'	System	04 Sep 2020 23:08:03

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 3'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:47:58', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f8909998-aaae-4340-8dc5-dffbb7871252'	System	05 Sep 2020 17:48:17
User entered 'Yes (Y)'	System	05 Sep 2020 17:48:17



US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:07', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f8909998-aaae-4340-8dc5-dffbb7871252'	System	05 Sep 2020 17:48:17
User entered '98.1'	System	05 Sep 2020 17:48:17

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:10', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f8909998-aaae-4340-8dc5-dffbb7871252'	System	05 Sep 2020 17:48:17
User entered 'No (N)'	System	05 Sep 2020 17:48:17

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f8909998-aaae-4340-8dc5-dffbb7871252'	System	05 Sep 2020 17:48:17
User entered '05 Sep 2020 12:48'	System	05 Sep 2020 17:48:17

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 4'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:22:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '18ecb313-af4b-4aed-b59d-f2dda7a648e6'	System	06 Sep 2020 20:23:11
User entered 'Yes (Y)'	System	06 Sep 2020 20:23:11

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:22:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '18ecb313-af4b-4aed-b59d-f2dda7a648e6'	System	06 Sep 2020 20:23:11
User entered '97.2'	System	06 Sep 2020 20:23:11



US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '18ecb313-af4b-4aed-b59d-f2dda7a648e6'	System	06 Sep 2020 20:23:11
User entered 'No (N)'	System	06 Sep 2020 20:23:11

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:05', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '18ecb313-af4b-4aed-b59d-f2dda7a648e6'	System	06 Sep 2020 20:23:11
User entered '06 Sep 2020 15:23'	System	06 Sep 2020 20:23:11

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 5'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4d326cb1-efc5-4e38-98bd-8e6814a37836'	System	07 Sep 2020 17:02:32
User entered 'Yes (Y)'	System	07 Sep 2020 17:02:32

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:16', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4d326cb1-efc5-4e38-98bd-8e6814a37836'	System	07 Sep 2020 17:02:32
User entered '97.5'	System	07 Sep 2020 17:02:32

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:23', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4d326cb1-efc5-4e38-98bd-8e6814a37836'	System	07 Sep 2020 17:02:32
User entered 'No (N)'	System	07 Sep 2020 17:02:32



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4d326cb1-efc5-4e38-98bd-8e6814a37836'	System	07 Sep 2020 17:02:32
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 17:02:32

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 6'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:17', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae87d6c7-691e-4f71-bd40-1d8f66750d04'	System	09 Sep 2020 08:04:39
User entered 'Yes (Y)'	System	09 Sep 2020 08:04:39

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:22', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae87d6c7-691e-4f71-bd40-1d8f66750d04'	System	09 Sep 2020 08:04:39
User entered '98.3'	System	09 Sep 2020 08:04:39

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae87d6c7-691e-4f71-bd40-1d8f66750d04'	System	09 Sep 2020 08:04:39
User entered 'No (N)'	System	09 Sep 2020 08:04:39

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:29', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ae87d6c7-691e-4f71-bd40-1d8f66750d04'	System	09 Sep 2020 08:04:39
User entered '09 Sep 2020 03:04'	System	09 Sep 2020 08:04:39



US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 7'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:40:57', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31ffc26d-4342-45e6-a5d9-d6548ef2a1f7'	System	10 Sep 2020 01:41:13
User entered 'Yes (Y)'	System	10 Sep 2020 01:41:13

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31ffc26d-4342-45e6-a5d9-d6548ef2a1f7'	System	10 Sep 2020 01:41:13
User entered '97.8'	System	10 Sep 2020 01:41:13

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:07', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31ffc26d-4342-45e6-a5d9-d6548ef2a1f7'	System	10 Sep 2020 01:41:13
User entered 'No (N)'	System	10 Sep 2020 01:41:13

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:09', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '31ffc26d-4342-45e6-a5d9-d6548ef2a1f7'	System	10 Sep 2020 01:41:13
User entered '09 Sep 2020 20:41'	System	10 Sep 2020 01:41:13

US3032112

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:08', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0bc7055d-4f85-4703-8422-27bb2a0b0a25'	System	03 Sep 2020 14:40:38
User entered 'None (1)'	System	03 Sep 2020 14:40:38

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:24', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0bc7055d-4f85-4703-8422-27bb2a0b0a25'	System	03 Sep 2020 14:40:38
User entered 'No (N)'	System	03 Sep 2020 14:40:38

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:28', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0bc7055d-4f85-4703-8422-27bb2a0b0a25'	System	03 Sep 2020 14:40:38
User entered 'No (N)'	System	03 Sep 2020 14:40:38

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:30', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0bc7055d-4f85-4703-8422-27bb2a0b0a25'	System	03 Sep 2020 14:40:38
User entered 'None (1)'	System	03 Sep 2020 14:40:38

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:32', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0bc7055d-4f85-4703-8422-27bb2a0b0a25'	System	03 Sep 2020 14:40:38
User entered '03 Sep 2020 09:40'	System	03 Sep 2020 14:40:38

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 09:27'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 11:57'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:39:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '462996ad-98fe-444c-89fa-a5504fb48268'	System	04 Sep 2020 05:40:09
User entered 'None (1)'	System	04 Sep 2020 05:40:09

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:39:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '462996ad-98fe-444c-89fa-a5504fb48268'	System	04 Sep 2020 05:40:09
User entered 'No (N)'	System	04 Sep 2020 05:40:09

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:39:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '462996ad-98fe-444c-89fa-a5504fb48268'	System	04 Sep 2020 05:40:09
User entered 'No (N)'	System	04 Sep 2020 05:40:09

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:40:03', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '462996ad-98fe-444c-89fa-a5504fb48268'	System	04 Sep 2020 05:40:09
User entered 'None (1)'	System	04 Sep 2020 05:40:09

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:40:06', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '462996ad-98fe-444c-89fa-a5504fb48268'	System	04 Sep 2020 05:40:09
User entered '04 Sep 2020 00:40'	System	04 Sep 2020 05:40:09

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 12:52'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 2'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:07:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '49d9e12a-275d-4eea-82bd-dbc94eb30655'	System	04 Sep 2020 23:08:11
User entered 'None (1)'	System	04 Sep 2020 23:08:11

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '49d9e12a-275d-4eea-82bd-dbc94eb30655'	System	04 Sep 2020 23:08:11
User entered 'No (N)'	System	04 Sep 2020 23:08:11

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:02', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '49d9e12a-275d-4eea-82bd-dbc94eb30655'	System	04 Sep 2020 23:08:11
User entered 'No (N)'	System	04 Sep 2020 23:08:11

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '49d9e12a-275d-4eea-82bd-dbc94eb30655'	System	04 Sep 2020 23:08:11
User entered 'None (1)'	System	04 Sep 2020 23:08:11

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:06', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '49d9e12a-275d-4eea-82bd-dbc94eb30655'	System	04 Sep 2020 23:08:11
User entered '04 Sep 2020 18:08'	System	04 Sep 2020 23:08:11

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 3'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:22', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '289dbe88-271c-4f29-9e26-1b53a3a9e8e1'	System	05 Sep 2020 17:48:35
User entered 'None (1)'	System	05 Sep 2020 17:48:35

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:24', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '289dbe88-271c-4f29-9e26-1b53a3a9e8e1'	System	05 Sep 2020 17:48:35
User entered 'No (N)'	System	05 Sep 2020 17:48:35

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '289dbe88-271c-4f29-9e26-1b53a3a9e8e1'	System	05 Sep 2020 17:48:35
User entered 'No (N)'	System	05 Sep 2020 17:48:35

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:28', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '289dbe88-271c-4f29-9e26-1b53a3a9e8e1'	System	05 Sep 2020 17:48:35
User entered 'None (1)'	System	05 Sep 2020 17:48:35

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:30', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '289dbe88-271c-4f29-9e26-1b53a3a9e8e1'	System	05 Sep 2020 17:48:35
User entered '05 Sep 2020 12:48'	System	05 Sep 2020 17:48:35

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 4'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:10', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bbd80240-7b57-4639-a4f7-ce9ff00201c3'	System	06 Sep 2020 20:23:37
User entered 'None (1)'	System	06 Sep 2020 20:23:37

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:11', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bbd80240-7b57-4639-a4f7-ce9ff00201c3'	System	06 Sep 2020 20:23:37
User entered 'No (N)'	System	06 Sep 2020 20:23:37

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:27', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bbd80240-7b57-4639-a4f7-ce9ff00201c3'	System	06 Sep 2020 20:23:37
User entered 'No (N)'	System	06 Sep 2020 20:23:37

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:29', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bbd80240-7b57-4639-a4f7-ce9ff00201c3'	System	06 Sep 2020 20:23:37
User entered 'None (1)'	System	06 Sep 2020 20:23:37

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:31', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bbd80240-7b57-4639-a4f7-ce9ff00201c3'	System	06 Sep 2020 20:23:37
User entered '06 Sep 2020 15:23'	System	06 Sep 2020 20:23:37

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 5'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:29', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bca59419-9622-4bf7-a4b7-6ac10bae7ba3'	System	07 Sep 2020 17:02:54
User entered 'None (1)'	System	07 Sep 2020 17:02:54

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bca59419-9622-4bf7-a4b7-6ac10bae7ba3'	System	07 Sep 2020 17:02:54
User entered 'No (N)'	System	07 Sep 2020 17:02:54

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:39', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bca59419-9622-4bf7-a4b7-6ac10bae7ba3'	System	07 Sep 2020 17:02:54
User entered 'No (N)'	System	07 Sep 2020 17:02:54

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bca59419-9622-4bf7-a4b7-6ac10bae7ba3'	System	07 Sep 2020 17:02:54
User entered 'None (1)'	System	07 Sep 2020 17:02:54

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:02:47', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bca59419-9622-4bf7-a4b7-6ac10bae7ba3'	System	07 Sep 2020 17:02:54
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 17:02:54

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 6'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:33', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b42b9911-3690-4136-9702-f53e0592ca08'	System	09 Sep 2020 08:04:51
User entered 'None (1)'	System	09 Sep 2020 08:04:51

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:36', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b42b9911-3690-4136-9702-f53e0592ca08'	System	09 Sep 2020 08:04:51
User entered 'No (N)'	System	09 Sep 2020 08:04:51

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:38', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b42b9911-3690-4136-9702-f53e0592ca08'	System	09 Sep 2020 08:04:51
User entered 'No (N)'	System	09 Sep 2020 08:04:51

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:41', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b42b9911-3690-4136-9702-f53e0592ca08'	System	09 Sep 2020 08:04:51
User entered 'None (1)'	System	09 Sep 2020 08:04:51

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'b42b9911-3690-4136-9702-f53e0592ca08'	System	09 Sep 2020 08:04:51
User entered '09 Sep 2020 03:04'	System	09 Sep 2020 08:04:51

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 7'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:14', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f2ed1847-3cfa-41ea-bc2b-46aaa32a77ea'	System	10 Sep 2020 01:41:26
User entered 'None (1)'	System	10 Sep 2020 01:41:26

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:16', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f2ed1847-3cfa-41ea-bc2b-46aaa32a77ea'	System	10 Sep 2020 01:41:26
User entered 'No (N)'	System	10 Sep 2020 01:41:26

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:18', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f2ed1847-3cfa-41ea-bc2b-46aaa32a77ea'	System	10 Sep 2020 01:41:26
User entered 'No (N)'	System	10 Sep 2020 01:41:26

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:19', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f2ed1847-3cfa-41ea-bc2b-46aaa32a77ea'	System	10 Sep 2020 01:41:26
User entered 'None (1)'	System	10 Sep 2020 01:41:26

US3032112

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:47:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:22', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'f2ed1847-3cfa-41ea-bc2b-46aaa32a77ea'	System	10 Sep 2020 01:41:26
User entered '09 Sep 2020 20:41'	System	10 Sep 2020 01:41:26

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:38', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered 'None (0)'	System	03 Sep 2020 14:40:51

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered 'None (0)'	System	03 Sep 2020 14:40:51

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:41', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered 'None (0)'	System	03 Sep 2020 14:40:51

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered 'None (0)'	System	03 Sep 2020 14:40:51

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:43', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered 'None (0)'	System	03 Sep 2020 14:40:51

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered 'None (0)'	System	03 Sep 2020 14:40:51



US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:46', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered 'No (N)'	System	03 Sep 2020 14:40:51

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-03T09:40:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1664d244-b614-42eb-ab29-0f2ac7472d51'	System	03 Sep 2020 14:40:51
User entered '03 Sep 2020 09:40'	System	03 Sep 2020 14:40:51

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 09:27'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 11:57'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:40:09', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecdf'	System	04 Sep 2020 12:23:03
User entered 'None (0)'	System	04 Sep 2020 12:23:03

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:40:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecdf'	System	04 Sep 2020 12:23:03
User entered 'None (0)'	System	04 Sep 2020 12:23:03

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:40:16', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecdf'	System	04 Sep 2020 12:23:03
User entered 'No interference with activity (1)'	System	04 Sep 2020 12:23:03



US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:40:19', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecdf'	System	04 Sep 2020 12:23:03
User entered 'None (0)'	System	04 Sep 2020 12:23:03

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:40:23', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecd'	System	04 Sep 2020 12:23:03
User entered 'None (0)'	System	04 Sep 2020 12:23:03

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T00:53:20', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecdf'	System	04 Sep 2020 12:23:03
User entered 'Some interference with activity not requiring medical attention (2)'	System	04 Sep 2020 12:23:03

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T07:22:55', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecdf'	System	04 Sep 2020 12:23:03
User entered 'No (N)'	System	04 Sep 2020 12:23:03

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T07:22:58', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '4a1eb5dd-0851-4422-86c5-17394215ecdf'	System	04 Sep 2020 12:23:03
User entered '04 Sep 2020 07:22'	System	04 Sep 2020 12:23:03

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '03 Sep 2020 12:52'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 2'	System	03 Sep 2020 14:18:47



US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:12', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:08:39

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:15', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered 'None (0)'	System	04 Sep 2020 23:08:39

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:17', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered 'None (0)'	System	04 Sep 2020 23:08:39

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:20', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered 'None (0)'	System	04 Sep 2020 23:08:39

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:24', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered 'None (0)'	System	04 Sep 2020 23:08:39

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered 'None (0)'	System	04 Sep 2020 23:08:39

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:32', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered 'No (N)'	System	04 Sep 2020 23:08:39

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-04T18:08:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '78ae5ff2-6089-41d0-9bae-516bf42c7020'	System	04 Sep 2020 23:08:39
User entered '04 Sep 2020 18:08'	System	04 Sep 2020 23:08:39



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 3'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:34', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0'	System	05 Sep 2020 17:49:15
User entered 'None (0)'	System	05 Sep 2020 17:49:15

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0'	System	05 Sep 2020 17:49:15
User entered 'None (0)'	System	05 Sep 2020 17:49:15

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:37', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0'	System	05 Sep 2020 17:49:15
User entered 'None (0)'	System	05 Sep 2020 17:49:15

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:38', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0' User entered 'None (0)'	System	05 Sep 2020 17:49:15
	System	05 Sep 2020 17:49:15

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:49', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0'	System	05 Sep 2020 17:49:15
User entered 'None (0)'	System	05 Sep 2020 17:49:15



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:50', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0' User entered 'None (0)'	System	05 Sep 2020 17:49:15
	System	05 Sep 2020 17:49:15

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:48:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0'	System	05 Sep 2020 17:49:15
User entered 'No (N)'	System	05 Sep 2020 17:49:15

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-05T12:49:09', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '901b5d41-bd70-43a3-ad06-6dc579de3eb0'	System	05 Sep 2020 17:49:15
User entered '05 Sep 2020 12:49'	System	05 Sep 2020 17:49:15

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:47:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 4'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered 'None (0)'	System	06 Sep 2020 20:23:54

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:36', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered 'None (0)'	System	06 Sep 2020 20:23:54



US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:37', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered 'None (0)'	System	06 Sep 2020 20:23:54

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:39', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered 'None (0)'	System	06 Sep 2020 20:23:54

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered 'None (0)'	System	06 Sep 2020 20:23:54

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered 'None (0)'	System	06 Sep 2020 20:23:54

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:45', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered 'No (N)'	System	06 Sep 2020 20:23:54

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:47:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-06T15:23:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd2d1afbb-03cc-4161-a4ec-19c0724b7266'	System	06 Sep 2020 20:23:54
User entered '06 Sep 2020 15:23'	System	06 Sep 2020 20:23:54

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:18:47



US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 5'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:10', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered 'None (0)'	System	07 Sep 2020 17:03:34

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:13', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered 'None (0)'	System	07 Sep 2020 17:03:34

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:14', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered 'None (0)'	System	07 Sep 2020 17:03:34

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:16', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered 'None (0)'	System	07 Sep 2020 17:03:34

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:18', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered 'None (0)'	System	07 Sep 2020 17:03:34

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:20', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered 'None (0)'	System	07 Sep 2020 17:03:34

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:22', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered 'No (N)'	System	07 Sep 2020 17:03:34



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-07T12:03:26', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'dc9f46e6-bbd6-4e93-9ecb-d2edd70d4ffc'	System	07 Sep 2020 17:03:34
User entered '07 Sep 2020 12:03'	System	07 Sep 2020 17:03:34

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 6'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:49', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered 'None (0)'	System	09 Sep 2020 08:05:16

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:51', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered 'None (0)'	System	09 Sep 2020 08:05:16

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered 'None (0)'	System	09 Sep 2020 08:05:16

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:55', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered 'None (0)'	System	09 Sep 2020 08:05:16



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:04:58', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered 'None (0)'	System	09 Sep 2020 08:05:16

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:05:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered 'None (0)'	System	09 Sep 2020 08:05:16

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:05:04', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered 'No (N)'	System	09 Sep 2020 08:05:16

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T03:05:07', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '16711748-5a0b-4354-b175-60b1930e12a5'	System	09 Sep 2020 08:05:16
User entered '09 Sep 2020 03:05'	System	09 Sep 2020 08:05:16

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	03 Sep 2020 14:18:47
User entered 'Day 7'	System	03 Sep 2020 14:18:47

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:25', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f'	System	10 Sep 2020 01:41:41
User entered 'None (0)'	System	10 Sep 2020 01:41:41



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:27', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f'	System	10 Sep 2020 01:41:41
User entered 'None (0)'	System	10 Sep 2020 01:41:41

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:28', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f' User entered 'None (0)'	System	10 Sep 2020 01:41:41
	System	10 Sep 2020 01:41:41

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:30', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f' User entered 'None (0)'	System	10 Sep 2020 01:41:41
	System	10 Sep 2020 01:41:41

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:31', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f'	System	10 Sep 2020 01:41:41
User entered 'None (0)'	System	10 Sep 2020 01:41:41

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:33', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f'	System	10 Sep 2020 01:41:41
User entered 'None (0)'	System	10 Sep 2020 01:41:41

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f'	System	10 Sep 2020 01:41:41
User entered 'No (N)'	System	10 Sep 2020 01:41:41

**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-09-09T20:41:37', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3963e4d9-16e0-494b-904e-8fa3cd3df08f'	System	10 Sep 2020 01:41:41
User entered '09 Sep 2020 20:41'	System	10 Sep 2020 01:41:41

US3032112

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:47:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:18:47



**US3032112**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:47:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:18:47

**US3032112**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:48:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 18:16:10

**US3032112**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:48:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '10 Sep 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 18:16:10

US3032112

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:48:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 18:16:10

**US3032112**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:48:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 18:16:10

US3032112

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		07 Apr 2021 21:48:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
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	10 Sep 2020 18:16:16
User entered 'Yes (Y)' reason for change: Data Entry Error	System	10 Sep 2020 18:16:16
User opened query 'Data is required. Please complete.' (Site from System).	Samantha Wieseler (b) (4)	10 Sep 2020 18:16:16
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	10 Sep 2020 18:16:13
	(b) (4)	

**US3032112**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '1'	System	10 Sep 2020 18:16:16
User entered empty.	System	10 Sep 2020 18:16:13

US3032112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		23 Feb 2021 16:50:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:41:36



US3032112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		23 Feb 2021 16:50:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:41:36

US3032112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		23 Feb 2021 16:50:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:41:36

US3032112

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		23 Feb 2021 16:50:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:41:36

US3032112

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		23 Feb 2021 16:50:27
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:41:42

**US3032112**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	17 Sep 2020 17:41:42

**US3032112**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:39:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 21:38:00

**US3032112**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:39:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered '24 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 21:38:00

US3032112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:39:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 21:38:00



US3032112

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:39:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 21:38:00

US3032112

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		23 Feb 2021 16:53:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	25 Sep 2020 21:38:03

**US3032112**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	25 Sep 2020 21:38:03

US3032112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:27:06
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:38

US3032112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:27:06
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '29 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:38

US3032112

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:27:06
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:38

**US3032112**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'VISIT3'	System	29 Sep 2020 14:00:38

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54



US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '29 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '08:07'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

**US3032112**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '29 Sep 2020 08:07'	System	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

**US3032112**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '74'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

**US3032112**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'bpm'	System	29 Sep 2020 14:00:54



US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'breaths/min'	System	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '105'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

**US3032112**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:03
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '66'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'mmHg'	System	29 Sep 2020 14:00:54

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18

US3032112

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18



US3032112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:48
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:01:07

US3032112

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:48
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '29 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:01:07

US3032112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:58
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:05:07

US3032112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:58
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered '29 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:05:07

US3032112

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:30:58
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '08:35' reason for change: Data Entry Error	System	29 Sep 2020 14:20:14
User opened query 'Data is required. Please provide.' (Site from System).	Kelsey Kelley (b) (4)	29 Sep 2020 14:20:14
User entered empty.	(b) (4)	
	System	29 Sep 2020 14:05:07
	Kelsey Kelley (b) (4)	29 Sep 2020 14:05:07
	(b) (4)	

**US3032112**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered '29 Sep 2020 08:35'	System	29 Sep 2020 14:20:14
User entered empty.	System	29 Sep 2020 14:05:07

US3032112

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:31:01
User signature succeeded.	Keith Vrbicky (b) (4)	29 Sep 2020 18:21:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 14:20:35

**US3032112**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	29 Sep 2020 14:20:35



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 64'	System	06 Aug 2020 01:48:14

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

[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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-05T23:46:05', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd589ad0c-c493-4dd9-a808-ab63b5c913e6'	System	06 Oct 2020 04:46:22
User entered 'No (N)'	System	06 Oct 2020 04:46:22

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-05T23:46:11', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd589ad0c-c493-4dd9-a808-ab63b5c913e6'	System	06 Oct 2020 04:46:22
User entered 'No (N)'	System	06 Oct 2020 04:46:22

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-05T23:46:14', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd589ad0c-c493-4dd9-a808-ab63b5c913e6'	System	06 Oct 2020 04:46:22
User entered '05 Oct 2020 23:46:14'	System	06 Oct 2020 04:46:22

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '05 Oct 2020 00:01'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '09 Oct 2020 23:59'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 71'	System	06 Aug 2020 01:48:14

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

[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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-12T07:08:21', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '90401b04-8dd5-4d2f-9dc9-49a968f25a95'	System	12 Oct 2020 12:08:37
User entered 'No (N)'	System	12 Oct 2020 12:08:37



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-12T07:08:29', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '90401b04-8dd5-4d2f-9dc9-49a968f25a95'	System	12 Oct 2020 12:08:37
User entered 'No (N)'	System	12 Oct 2020 12:08:37

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-12T07:08:31', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '90401b04-8dd5-4d2f-9dc9-49a968f25a95'	System	12 Oct 2020 12:08:37
User entered '12 Oct 2020 07:08:31'	System	12 Oct 2020 12:08:37

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '12 Oct 2020 00:01'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '16 Oct 2020 23:59'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 78'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-19T07:39:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '44ce61fc-d497-41dc-9f4f-b72b2f877fd3'	System	19 Oct 2020 12:39:52
User entered 'No (N)'	System	19 Oct 2020 12:39:52

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-19T07:39:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '44ce61fc-d497-41dc-9f4f-b72b2f877fd3'	System	19 Oct 2020 12:39:52
User entered 'No (N)'	System	19 Oct 2020 12:39:52

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-10-19T07:39:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '44ce61fc-d497-41dc-9f4f-b72b2f877fd3'	System	19 Oct 2020 12:39:52
User entered '19 Oct 2020 07:39:48'	System	19 Oct 2020 12:39:52



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '19 Oct 2020 00:01'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '23 Oct 2020 23:59'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 92'	System	06 Aug 2020 01:48:14

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

[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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-03T07:58:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7c808dc1-d0f1-46fe-b9ce-fafbfd72a2f8'	System	03 Nov 2020 13:58:39
User entered 'No (N)'	System	03 Nov 2020 13:58:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-03T07:58:31', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7c808dc1-d0f1-46fe-b9ce-fafbfd72a2f8'	System	03 Nov 2020 13:58:39
User entered 'No (N)'	System	03 Nov 2020 13:58:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-03T07:58:34', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7c808dc1-d0f1-46fe-b9ce-fafbfd72a2f8'	System	03 Nov 2020 13:58:39
User entered '03 Nov 2020 07:58:34'	System	03 Nov 2020 13:58:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '02 Nov 2020 00:01'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '06 Nov 2020 23:59'	System	06 Aug 2020 01:48:14



US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 99'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-10T11:19:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '18507e14-66b2-423d-a413-f94120121512'	System	10 Nov 2020 17:19:55
User entered 'No (N)'	System	10 Nov 2020 17:19:55

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-10T11:19:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '18507e14-66b2-423d-a413-f94120121512'	System	10 Nov 2020 17:19:55
User entered 'No (N)'	System	10 Nov 2020 17:19:55

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-10T11:19:50', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '18507e14-66b2-423d-a413-f94120121512'	System	10 Nov 2020 17:19:55
User entered '10 Nov 2020 11:19:50'	System	10 Nov 2020 17:19:55

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '09 Nov 2020 00:01'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '13 Nov 2020 23:59'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered 'Day 106'	System	06 Aug 2020 01:48:14

US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

[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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-16T10:42:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7ec2689e-95fd-4070-aa5d-873472b0b718'	System	17 Nov 2020 04:15:52
User entered 'No (N)'	System	17 Nov 2020 04:15:52



US3032112

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-16T22:15:41', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7ec2689e-95fd-4070-aa5d-873472b0b718'	System	17 Nov 2020 04:15:52
User entered 'No (N)'	System	17 Nov 2020 04:15:52

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-16T22:15:43', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7ec2689e-95fd-4070-aa5d-873472b0b718'	System	17 Nov 2020 04:15:52
User entered '16 Nov 2020 22:15:43'	System	17 Nov 2020 04:15:52

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '16 Nov 2020 00:01'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:54
Data entry locked.	System	06 Aug 2020 01:48:14
User entered '20 Nov 2020 23:59'	System	06 Aug 2020 01:48:14

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2020-11-24T23:12:51', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '789ceb57-da66-4b1c-8435-0eda2a5b560a'	System	25 Nov 2020 05:13:04
User entered 'No (N)'	System	25 Nov 2020 05:13:04

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2020-11-24T23:12:55', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '789ceb57-da66-4b1c-8435-0eda2a5b560a'	System	25 Nov 2020 05:13:04
User entered 'No (N)'	System	25 Nov 2020 05:13:04

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-24T23:12:58', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '789ceb57-da66-4b1c-8435-0eda2a5b560a'	System	25 Nov 2020 05:13:04
User entered '24 Nov 2020 23:12:58'	System	25 Nov 2020 05:13:04



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2020-11-27T05:34:14', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '321e6d26-b48f-48b2-a49c-a5bb334d837d'	System	27 Nov 2020 11:34:24
User entered 'No (N)'	System	27 Nov 2020 11:34:24

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2020-11-27T05:34:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '321e6d26-b48f-48b2-a49c-a5bb334d837d'	System	27 Nov 2020 11:34:24
User entered 'No (N)'	System	27 Nov 2020 11:34:24

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-11-27T05:34:19', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '321e6d26-b48f-48b2-a49c-a5bb334d837d'	System	27 Nov 2020 11:34:24
User entered '27 Nov 2020 05:34:19'	System	27 Nov 2020 11:34:24

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2020-12-05T02:24:32', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7c40d7f2-9914-4134-b302-51d2188c5eb7'	System	05 Dec 2020 08:24:42
User entered 'No (N)'	System	05 Dec 2020 08:24:42

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2020-12-05T02:24:34', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7c40d7f2-9914-4134-b302-51d2188c5eb7'	System	05 Dec 2020 08:24:42
User entered 'No (N)'	System	05 Dec 2020 08:24:42

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-12-05T02:24:37', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7c40d7f2-9914-4134-b302-51d2188c5eb7'	System	05 Dec 2020 08:24:42
User entered '05 Dec 2020 02:24:37'	System	05 Dec 2020 08:24:42

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2020-12-12T02:01:44', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9858912a-c578-4427-b8fb-1a26c97fb456'	System	12 Dec 2020 08:01:56
User entered 'No (N)'	System	12 Dec 2020 08:01:56



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2020-12-12T02:01:48', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9858912a-c578-4427-b8fb-1a26c97fb456'	System	12 Dec 2020 08:01:56
User entered 'No (N)'	System	12 Dec 2020 08:01:56

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-12-12T02:01:51', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '9858912a-c578-4427-b8fb-1a26c97fb456'	System	12 Dec 2020 08:01:56
User entered '12 Dec 2020 02:01:51'	System	12 Dec 2020 08:01:56

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2020-12-20T22:31:53', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '675557a8-af36-4f74-8582-6b8ac0926277'	System	21 Dec 2020 04:32:04
User entered 'No (N)'	System	21 Dec 2020 04:32:04

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2020-12-20T22:31:55', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '675557a8-af36-4f74-8582-6b8ac0926277'	System	21 Dec 2020 04:32:04
User entered 'No (N)'	System	21 Dec 2020 04:32:04

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-12-20T22:31:57', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '675557a8-af36-4f74-8582-6b8ac0926277'	System	21 Dec 2020 04:32:04
User entered '20 Dec 2020 22:31:57'	System	21 Dec 2020 04:32:04



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2020-12-25T00:10:05', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '51f28ccc-5893-42ba-97dd-4e6caf7fab2e'	System	25 Dec 2020 06:10:17
User entered 'No (N)'	System	25 Dec 2020 06:10:17

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2020-12-25T00:10:08', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '51f28ccc-5893-42ba-97dd-4e6caf7fab2e'	System	25 Dec 2020 06:10:17
User entered 'No (N)'	System	25 Dec 2020 06:10:17

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2020-12-25T00:10:10', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '51f28ccc-5893-42ba-97dd-4e6caf7fab2e'	System	25 Dec 2020 06:10:17
User entered '25 Dec 2020 00:10:10'	System	25 Dec 2020 06:10:17

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-01-04T17:32:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '993c623f-af06-41b7-b3b2-ac71bc2af6aa'	System	04 Jan 2021 23:32:54
User entered 'No (N)'	System	04 Jan 2021 23:32:54

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-01-04T17:32:45', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '993c623f-af06-41b7-b3b2-ac71bc2af6aa'	System	04 Jan 2021 23:32:54
User entered 'No (N)'	System	04 Jan 2021 23:32:54

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-01-04T17:32:47', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '993c623f-af06-41b7-b3b2-ac71bc2af6aa'	System	04 Jan 2021 23:32:54
User entered '04 Jan 2021 17:32:47'	System	04 Jan 2021 23:32:54

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-01-18T15:51:38', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '230e2ac7-2ec5-49d6-b9bf-b5279b9da6fd'	System	18 Jan 2021 21:51:50
User entered 'No (N)'	System	18 Jan 2021 21:51:50

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-01-18T15:51:40', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '230e2ac7-2ec5-49d6-b9bf-b5279b9da6fd'	System	18 Jan 2021 21:51:50
User entered 'No (N)'	System	18 Jan 2021 21:51:50

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-01-18T15:51:42', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '230e2ac7-2ec5-49d6-b9bf-b5279b9da6fd'	System	18 Jan 2021 21:51:50
User entered '18 Jan 2021 15:51:42'	System	18 Jan 2021 21:51:50

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-01-29T00:33:32', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '79a8a866-3157-4f71-854e-4e08b7c5bb0f'	System	29 Jan 2021 06:33:47
User entered 'No (N)'	System	29 Jan 2021 06:33:47

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-01-29T00:33:35', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '79a8a866-3157-4f71-854e-4e08b7c5bb0f'	System	29 Jan 2021 06:33:47
User entered 'No (N)'	System	29 Jan 2021 06:33:47

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-01-29T00:33:38', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '79a8a866-3157-4f71-854e-4e08b7c5bb0f' User entered '29 Jan 2021 00:33:38'	System	29 Jan 2021 06:33:47

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-02-05T07:56:52', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3e41f8f4-1528-4d8b-9d0b-1594f998b98f'	System	05 Feb 2021 13:57:03
User entered 'No (N)'	System	05 Feb 2021 13:57:03

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-02-05T07:56:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3e41f8f4-1528-4d8b-9d0b-1594f998b98f'	System	05 Feb 2021 13:57:03
User entered 'No (N)'	System	05 Feb 2021 13:57:03

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-02-05T07:56:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '3e41f8f4-1528-4d8b-9d0b-1594f998b98f' User entered '05 Feb 2021 07:56:59'	System	05 Feb 2021 13:57:03

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-02-12T09:13:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7506a266-6410-4847-a6c7-cb50690cc298'	System	12 Feb 2021 15:14:10
User entered 'No (N)'	System	12 Feb 2021 15:14:10



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-02-12T09:14:01', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7506a266-6410-4847-a6c7-cb50690cc298'	System	12 Feb 2021 15:14:10
User entered 'No (N)'	System	12 Feb 2021 15:14:10

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-02-12T09:14:03', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '7506a266-6410-4847-a6c7-cb50690cc298'	System	12 Feb 2021 15:14:10
User entered '12 Feb 2021 09:14:03'	System	12 Feb 2021 15:14:10

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-02-19T17:56:56', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1d91c468-fe69-4405-890d-45f92746525f'	System	19 Feb 2021 23:57:09
User entered 'No (N)'	System	19 Feb 2021 23:57:09

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-02-19T17:56:59', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1d91c468-fe69-4405-890d-45f92746525f'	System	19 Feb 2021 23:57:09
User entered 'No (N)'	System	19 Feb 2021 23:57:09

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-02-19T17:57:02', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '1d91c468-fe69-4405-890d-45f92746525f' User entered '19 Feb 2021 17:57:02'	System	19 Feb 2021 23:57:09
	System	19 Feb 2021 23:57:09



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-02-28T21:47:20-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '94fa1847-f4d6-4108-ad67-7c5987e34abe'	System	01 Mar 2021 03:47:33
User entered 'No (N)'	System	01 Mar 2021 03:47:33

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-02-28T21:47:25-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '94fa1847-f4d6-4108-ad67-7c5987e34abe'	System	01 Mar 2021 03:47:33
User entered 'No (N)'	System	01 Mar 2021 03:47:33

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-02-28T21:47:28-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '94fa1847-f4d6-4108-ad67-7c5987e34abe' User entered '28 Feb 2021 21:47:28'	System	01 Mar 2021 03:47:33

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-03-05T02:40:36-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0492c412-7b9e-49af-baa5-8c8d48cfd1ed'	System	05 Mar 2021 08:40:51
User entered 'No (N)'	System	05 Mar 2021 08:40:51

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-03-05T02:40:40-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0492c412-7b9e-49af-baa5-8c8d48cfd1ed'	System	05 Mar 2021 08:40:51
User entered 'No (N)'	System	05 Mar 2021 08:40:51

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-03-05T02:40:42-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '0492c412-7b9e-49af-baa5-8c8d48cfd1ed'	System	05 Mar 2021 08:40:51
User entered '05 Mar 2021 02:40:42'	System	05 Mar 2021 08:40:51

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-03-12T00:12:58-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd795fe8c-1101-497d-b9a9-c41aae72d06b' User entered 'No (N)'	System	12 Mar 2021 06:13:13
	System	12 Mar 2021 06:13:13



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-03-12T00:13:05-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd795fe8c-1101-497d-b9a9-c41aae72d06b'	System	12 Mar 2021 06:13:13
User entered 'No (N)'	System	12 Mar 2021 06:13:13

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-03-12T00:13:07-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'd795fe8c-1101-497d-b9a9-c41aae72d06b' User entered '12 Mar 2021 00:13:07'	System	12 Mar 2021 06:13:13
	System	12 Mar 2021 06:13:13

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-03-28T18:18:08-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bc82a8dd-65e4-441d-a63f-cac7995d3e31'	System	28 Mar 2021 23:18:18
User entered 'No (N)'	System	28 Mar 2021 23:18:18

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-03-28T18:18:10-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bc82a8dd-65e4-441d-a63f-cac7995d3e31'	System	28 Mar 2021 23:18:18
User entered 'No (N)'	System	28 Mar 2021 23:18:18

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-03-28T18:18:13-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'bc82a8dd-65e4-441d-a63f-cac7995d3e31'	System	28 Mar 2021 23:18:18
User entered '28 Mar 2021 18:18:13'	System	28 Mar 2021 23:18:18

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-04-02T07:48:00-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '81ed5d70-0009-4087-b48c-2e2d1ef3e9d5'	System	02 Apr 2021 12:48:16
User entered 'No (N)'	System	02 Apr 2021 12:48:16

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-04-02T07:48:03-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '81ed5d70-0009-4087-b48c-2e2d1ef3e9d5'	System	02 Apr 2021 12:48:16
User entered 'No (N)'	System	02 Apr 2021 12:48:16



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-04-02T07:48:05-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '81ed5d70-0009-4087-b48c-2e2d1ef3e9d5'	System	02 Apr 2021 12:48:16
User entered '02 Apr 2021 07:48:05'	System	02 Apr 2021 12:48:16

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-04-09T09:08:46-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '57876305-03e2-4a31-af2c-e13821e4a66b' User entered 'No (N)'	System	09 Apr 2021 14:08:59

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-04-09T09:08:50-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '57876305-03e2-4a31-af2c-e13821e4a66b'	System	09 Apr 2021 14:08:59
User entered 'No (N)'	System	09 Apr 2021 14:08:59

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-04-09T09:08:52-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '57876305-03e2-4a31-af2c-e13821e4a66b' User entered '09 Apr 2021 09:08:52'	System	09 Apr 2021 14:08:59
	System	09 Apr 2021 14:08:59

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-04-16T20:49:31-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ab3a1955-0a4e-4053-ac3a-8d9bcf219b00'	System	17 Apr 2021 01:50:08
User entered 'No (N)'	System	17 Apr 2021 01:50:08

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-04-16T20:49:59-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ab3a1955-0a4e-4053-ac3a-8d9bcf219b00'	System	17 Apr 2021 01:50:08
User entered 'No (N)'	System	17 Apr 2021 01:50:08

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-04-16T20:50:02-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: 'ab3a1955-0a4e-4053-ac3a-8d9bcf219b00'	System	17 Apr 2021 01:50:08
User entered '16 Apr 2021 20:50:02'	System	17 Apr 2021 01:50:08

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-04-25T11:41:56-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2de77fa5-c297-4d01-9e68-8302532ff817'	System	25 Apr 2021 16:42:05
User entered 'No (N)'	System	25 Apr 2021 16:42:05

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-04-25T11:41:59-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2de77fa5-c297-4d01-9e68-8302532ff817'	System	25 Apr 2021 16:42:05
User entered 'No (N)'	System	25 Apr 2021 16:42:05

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-04-25T11:42:01-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2de77fa5-c297-4d01-9e68-8302532ff817'	System	25 Apr 2021 16:42:05
User entered '25 Apr 2021 11:42:01'	System	25 Apr 2021 16:42:05

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[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 (0512d75783591e5d)', Time: '2021-04-30T00:06:23-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2f2771ed-fa19-45b8-ac14-2673314c1aa3'	System	30 Apr 2021 05:06:37
User entered 'No (N)'	System	30 Apr 2021 05:06:37

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Have you been exposed to someone with 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 (0512d75783591e5d)', Time: '2021-04-30T00:06:26-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2f2771ed-fa19-45b8-ac14-2673314c1aa3'	System	30 Apr 2021 05:06:37
User entered 'No (N)'	System	30 Apr 2021 05:06:37



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-04-30T00:06:29-05:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '2f2771ed-fa19-45b8-ac14-2673314c1aa3'	System	30 Apr 2021 05:06:37
User entered '30 Apr 2021 00:06:29'	System	30 Apr 2021 05:06:37

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:03:39

**US3032112**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 14:03:39



**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 14:03:39

**US3032112**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:47:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:39
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 14:03:39

US3032112

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:47:59**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-02-28T21:47:35-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '90c746f4-f0ef-4a10-99dc-ddafb073b2cf'	System	01 Mar 2021 03:47:43
User entered 'No (N)'	System	01 Mar 2021 03:47:43

**US3032112**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0512d75783591e5d)', Time: '2021-02-28T21:47:38-06:00', User OID: 'PatientReportedOutcome (US3032112)', ODM File OID: '90c746f4-f0ef-4a10-99dc-ddafb073b2cf' User entered '28 Feb 2021 21:47:38'	System	01 Mar 2021 03:47:43
	System	01 Mar 2021 03:47:43

**US3032112**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:37:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:44:25

**US3032112**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:37:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User entered '27 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:44:25



**US3032112**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:37:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:44:25

**US3032112**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		21 Jan 2021 17:37:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:44:25

US3032112

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
DataPoint Verified.		02 Apr 2021 00:07:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:24:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:44:36

**US3032112**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:18
User entered 'I'	System	28 Oct 2020 13:44:36

**US3032112**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:49:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:57
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	02 Dec 2020 19:58:56

US3032112

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:49:31
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:59
Signature has been broken.	(b) (4) Chelsie Nutsch (b) (4)	15 Mar 2021 19:01:43
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	15 Mar 2021 19:01:43
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	08 Dec 2020 19:46:57
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4)	02 Dec 2020 19:58:56
	(b) (4)	

**US3032112**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:49:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Russell Herstein (b) (4) (b) (4)	02 Dec 2020 19:58:56

**US3032112**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:49:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:57
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	02 Dec 2020 19:58:56



**US3032112**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:49:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:57
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	02 Dec 2020 19:59:02

**US3032112**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
User entered 'I'	System	02 Dec 2020 19:59:02

US3032112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
User closed query 'Per the source this call was not completed on this date please refer to the source and update' (Site from CRA).		13 Apr 2021 14:12:31
DataPoint Verified.		13 Apr 2021 14:12:17
Query 'Per the source this call was not completed on this date please refer to the source and update' answered with 'source and edc have been updated to correct day call was made and match. ' (Site from CRA).	Samantha Wieseler (b) (4)	09 Apr 2021 16:33:55
User opened query 'Per the source this call was not completed on this date please refer to the source and update' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 21:51:24
DataPoint Verified.		23 Feb 2021 17:08:48
User signature succeeded.		23 Feb 2021 17:04:35
User entered 'Yes (Y)'	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 18:24:42

US3032112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		13 Apr 2021 14:12:45
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:05
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	09 Apr 2021 16:33:09
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	09 Apr 2021 16:33:09
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 17:08:50
DataPoint Verified.		23 Feb 2021 17:04:35
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:24:42

**US3032112**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		13 Apr 2021 14:12:45
DataPoint Un-verified.		23 Feb 2021 17:08:52
DataPoint Verified.		23 Feb 2021 17:04:35
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:24:42

US3032112

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		13 Apr 2021 14:12:45
DataPoint Un-verified.		23 Feb 2021 17:08:54
DataPoint Verified.		23 Feb 2021 17:04:35
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:24:42

US3032112

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		23 Feb 2021 17:07:02
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:24:48

**US3032112**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
User entered 'I'	System	01 Feb 2021 18:24:48



**US3032112**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:51:54
DataPoint Un-verified.		23 Feb 2021 17:08:30
DataPoint Verified.		23 Feb 2021 17:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered 'Yes (Y)'	(b) (4)	01 Feb 2021 19:20:55
	(b) (4), (b) (6)	

**US3032112**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:51:54
DataPoint Un-verified.		23 Feb 2021 17:08:32
DataPoint Verified.		23 Feb 2021 17:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:20:55

US3032112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:51:54
DataPoint Un-verified.		23 Feb 2021 17:08:34
DataPoint Verified.		23 Feb 2021 17:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:20:55

US3032112

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:51:54
DataPoint Un-verified.		23 Feb 2021 17:08:36
DataPoint Verified.		23 Feb 2021 17:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:20:55

US3032112

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
DataPoint Verified.		07 Apr 2021 21:51:57
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:20:59

**US3032112**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:30
User entered 'I'	System	01 Feb 2021 19:20:59

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:02
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:27

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:02
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '8 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:27



US3032112

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

[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 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:02
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:27

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered 'VISIT4'	System	08 Mar 2021 22:52:27

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered empty.	System	29 Mar 2021 21:08:40

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	



US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered empty.	System	29 Mar 2021 21:08:40

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered empty.	System	29 Mar 2021 21:08:40

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:47:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered empty.	System	29 Mar 2021 21:08:40

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:07
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:08:40
	(b) (4)	



US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered empty.	System	29 Mar 2021 21:08:40

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00

US3032112

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00

US3032112

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:17
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
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	08 Mar 2021 22:52:34
User entered 'No (N)' reason for change: Data Entry Error	System	08 Mar 2021 22:52:34
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	08 Mar 2021 22:52:34
User entered empty.	(b) (4)	
	System	08 Mar 2021 22:52:30
	Kelsey Kelley (b) (4)	08 Mar 2021 22:52:30
	(b) (4)	

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:47:59**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	627 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:17
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:30

US3032112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:25
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:44

US3032112

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:25
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '8 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:44

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:47:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	627 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:25
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '16:05'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:44



**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered '8 Mar 2021 16:05'	System	08 Mar 2021 22:52:44

US3032112

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	627 Apr 2021 10:50:00
DataPoint Verified.		07 Apr 2021 21:53:30
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:52:46

**US3032112**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:50:00
User entered 'I'	System	08 Mar 2021 22:52:46

**US3032112**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:15
DataPoint Verified.		07 Apr 2021 21:53:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:08:22

**US3032112**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:15
DataPoint Verified.		07 Apr 2021 21:53:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:08:22

**US3032112**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:47:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:15
DataPoint Verified.		07 Apr 2021 21:53:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:08:22

US3032112

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:15
DataPoint Verified.		07 Apr 2021 21:53:38
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:08:22

US3032112

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:15
DataPoint Verified.		07 Apr 2021 21:53:41
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:08:26



**US3032112**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:15
User entered 'I'	System	30 Mar 2021 19:08:26

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Jan 2021 19:09:12

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered '22 Jan 2021'	(b) (4)	
	Linden DeBoer (b) (4)	22 Jan 2021 19:09:12
	(b) (4)	

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[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 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:11
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Jan 2021 19:09:12

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:47:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 19:09:12

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:47:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered '22 Jan 2021'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Jan 2021 19:09:29

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:47:59**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:55:57
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:38:26

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:47:59**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	22 Jan 2021 19:09:29
	(b) (4)	



US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:47:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:55:57
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:38:26

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:47:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered '22 Jan 2021'	(b) (4)	
	Linden DeBoer (b) (4)	22 Jan 2021 19:09:29
	(b) (4)	

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:47:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered 'Placebo (Placebo)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Jan 2021 19:09:29

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:47:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered 'Placebo (Placebo)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Jan 2021 19:09:29

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:47:59**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered 'Placebo (Placebo)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	22 Jan 2021 19:09:29

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:47:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:34
User entered 'No (N)'	(b) (4)	
	Linden DeBoer (b) (4)	22 Jan 2021 19:09:29
	(b) (4)	

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:47:59**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '1'	System	22 Jan 2021 19:09:29

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:47:59**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered empty.	System	22 Jan 2021 19:09:29



US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:34
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:56:11

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:34
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '22 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:56:11

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:54:34
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '09:19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:56:11

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:47:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '22 Jan 2021 09:19'	System	08 Mar 2021 22:56:11

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:55:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:56:22

US3032112

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:55:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '22 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:56:22

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
DataPoint Verified.		07 Apr 2021 21:55:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '09:26'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:56:22

**US3032112**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:47:59**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:16:16
User entered '22 Jan 2021 09:26'	System	08 Mar 2021 22:56:22



US3032112

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:47:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:08:59
DataPoint Verified.		23 Feb 2021 16:08:27
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	10 Feb 2021 19:53:31

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:25
User entered 'USA-US032-2021-mRNA-1273-P301000007'	System	11 Feb 2021 18:41:20
User entered 'New'	(b) (4), (b) (6)	11 Feb 2021 18:41:20

US3032112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:59

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of limbs congenital, PT: Talipes, LLT: Talipes equinovarus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:24:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:24:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	19 Apr 2021 15:26:20
User closed query 'PV Query: Please report congenital anomaly (or type of congenital anomaly when available or known) as a SAE per protocol.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:33:09
User closed query 'PV Query: Please update 'pregnancy' event in the EDC to congenital anomaly (or type of congenital anomaly when available or known). Per protocol, only the pregnancy is reported on the Pregnancy Report Form.' (Site from Safety).		16 Apr 2021 18:33:05
User closed query 'Please clarify if this is "Bilateral Talipes Equinovarus of Fetus" ' (Site from CRA).		16 Apr 2021 13:52:47
Query 'Please clarify if this is "Bilateral Talipes Equinovarus of Fetus" ' answered with 'term has been updated. and clarified above question. ' (Site from CRA).	Samantha Wieseler (b) (4) (b) (4)	16 Apr 2021 12:51:17
User opened query 'Please clarify if this is "Bilateral Talipes Equinovarus of Fetus" ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 20:49:43
DataPoint Verified.		15 Apr 2021 20:45:39
Query 'PV Query: Please report congenital anomaly (or type of congenital anomaly when available or known) as a SAE per protocol.' answered with 'updated. thank you' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	15 Apr 2021 19:56:46
Query 'PV Query: Please update 'pregnancy' event in the EDC to congenital anomaly (or type of congenital anomaly when available or known). Per protocol, only the pregnancy is reported on the Pregnancy Report Form.' answered with 'updated. thank you' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	15 Apr 2021 19:56:39
Data point term sent to Coder	System	15 Apr 2021 19:56:34
DataPoint Un-verified.	Chelsie Nutsch (b) (4) (b) (4)	15 Apr 2021 19:55:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:59

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Chelsie Nutsch (b) (4)	15 Apr 2021 19:55:49
	(b) (4)	
Signature has been broken.	Chelsie Nutsch (b) (4)	15 Apr 2021 19:55:49
	(b) (4)	
User entered 'bilateral talipes equinovirus of fetus' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	15 Apr 2021 19:55:49
	(b) (4)	
User opened query 'PV Query: Please report congenital anomaly (or type of congenital anomaly when available or known) as a SAE per protocol.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:34:19
User opened query 'PV Query: Please update 'pregnancy' event in the EDC to congenital anomaly (or type of congenital anomaly when available or known). Per protocol, only the pregnancy is reported on the Pregnancy Report Form.' (Site from Safety).		15 Apr 2021 16:33:50
DataPoint Verified.		23 Feb 2021 16:08:19
User closed query 'PV Query: Please consider updating event term to the actual adverse event(s) that occurred.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:15:14
Query 'PV Query: Please consider updating event term to the actual adverse event(s) that occurred.' answered with 'pregnancy is the actual event.' (Site from Safety).	Samantha Wieseler (b) (4)	19 Feb 2021 18:08:49
	(b) (4)	
User opened query 'PV Query: Please consider updating event term to the actual adverse event(s) that occurred.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:07:12
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
	(b) (4)	
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLG: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\23.0.	Coder Import (b) (4)	10 Feb 2021 20:25:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Feb 2021 20:25:52
	(b) (4)	
Data point term sent to Coder	System	10 Feb 2021 20:24:39
User entered 'Pregnancy'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Yes (Y)'	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify the start date of the event, bilateral talipes equinovarus of fetus as it was provided as 11 Aug 2020. However, the estimated date of conception was listed as 25 Aug 2020. Please consider updating the SAE onset date. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:27:55
Query 'PV Query: Please clarify the start date of the event, bilateral talipes equinovarus of fetus as it was provided as 11 Aug 2020. However, the estimated date of conception was listed as 25 Aug 2020. Please consider updating the SAE onset date. If not, please clarify.' answered with 'estimated date of conception was estimated by subject. after receiving medical records date is correct as entered. ' (Site from Safety).	Samantha Wieseler (b) (4)	23 Apr 2021 12:52:33
User opened query 'PV Query: Please clarify the start date of the event, bilateral talipes equinovarus of fetus as it was provided as 11 Aug 2020. However, the estimated date of conception was listed as 25 Aug 2020. Please consider updating the SAE onset date. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 22:32:20
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '11 Aug 2020'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06



**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 20:24:06

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Yes (Y)'	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 20:24:06

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Yes (Y)'	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	



**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '0'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '0'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '0'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

US3032112

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '0'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06



**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'I'	(b) (4)	
	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '0'	(b) (4) Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

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**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	10 Feb 2021 20:24:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Linden DeBoer (b) (4)	10 Feb 2021 20:24:36
User entered '0'	(b) (4)	
	System	10 Feb 2021 20:24:06
	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '0'	(b) (4)	
	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '0'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered empty.	(b) (4) Linden DeBoer (b) (4)	10 Feb 2021 20:24:06
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = U/S. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 19:35:42
Query 'Per DM CLR: Narrative = U/S. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Added to Con Procedures' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	08 Mar 2021 22:54:44
User opened query 'Per DM CLR: Narrative = U/S. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 01:57:01
User closed query 'PV Query: Please provide the medical record for this subject be provided up to this point in time including the USN report, when available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:19:08
Query 'PV Query: Please provide the medical record for this subject be provided up to this point in time including the USN report, when available.' answered with 'medical records have been sent. ' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	25 Feb 2021 17:21:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:08:19
User opened query 'PV Query: Please provide the medical record for this subject be provided up to this point in time including the USN report, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:03:58
User closed query 'PV Query - Can you provide the medical record for this subject up to this point in time?' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:03:54
Query 'PV Query - Can you provide the medical record for this subject up to this point in time?' answered with 'subject was just seen yesterday will have subject sign medical release once they have their first dr appt' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	19 Feb 2021 21:16:23
User opened query 'PV Query - Can you provide the medical record for this subject up to this point in time?' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:10:08

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EAB) (1725)

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'Medical records have been received and reviewed. Subject reported pregnancy to the site on 22Jan2021 while at her participation decision visit. The subject was 24 weeks. Her LMP is 11Aug2020. Estimated due date is 18May2021. The subject was noted to have received placebo. Further vaccination was withheld. At the time of visit, 22Jan2021, subject stated her pregnancy was progressing well. While reviewing medical records it is noted that there are several congenital abnormalities noted. U/S and a follow up at a high risk OBGYN shows thick nuchal fold measuring 7.8mm and 9.4 mm at follow up. Bilateral talipes equinovirus, levoration of cardiac axis, and questionable abnormal profile. Per records review the subject is aware of abnormalities as of 31Dec2020 and did not report to the site. Will continue to follow pregnancy progression.'	(b) (4) Linden DeBoer (b) (4)	10 Feb 2021 20:24:06

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 20:24:06

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 20:24:06

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Pregnancy complicated by maternal disorders, PT: Gestational diabetes, LLT: Gestational diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Mar 2021 16:45:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:45:29
Data point term sent to Coder	System	25 Mar 2021 16:44:58
User entered 'gestational diabetes'	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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**Folder: Adverse Events**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '5 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

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**Folder: Adverse Events**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:44:11

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
DataPoint Un-verified.	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
DataPoint Un-verified.	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
User entered '28 Apr 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11



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**Folder: Adverse Events**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:44:11

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11



**US3032112**

**Folder: Adverse Events**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	



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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

US3032112

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
DataPoint Un-verified.	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kelsey Kelley (b) (4)	03 May 2021 14:46:36
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:47:59**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:26
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:44:11
	(b) (4)	

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 16:44:11

**US3032112**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 16:44:11



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:47:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:08:59
DataPoint Verified.		07 Apr 2021 22:02:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:55
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	25 Mar 2021 16:44:55
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 13:21:37
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:46:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:46:30
Data point term sent to Coder	System	25 Mar 2021 16:46:02
User entered 'acyclovir'	Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'genital herpes'	Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '400'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '08 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:45:43



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:45:43

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:45:43

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIBENCLAMIDE, PRODUCTSYNONYM: GLYBURIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 16:48:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:48:29
Data point term sent to Coder	System	25 Mar 2021 16:47:06
User entered 'glyburide'	Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'gestational diabetes'	Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '2.5'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '5 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Kelsey Kelley (b) (4)	03 May 2021 16:32:04
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	03 May 2021 16:32:04
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	03 May 2021 16:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20
	(b) (4)	



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Kelsey Kelley (b) (4)	03 May 2021 16:32:04
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	03 May 2021 16:32:04
	(b) (4)	
User entered '28 Apr 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	03 May 2021 16:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:02:58
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	25 Mar 2021 16:46:20

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 16:46:20

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:46:20

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:46:20

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: OXYTOCIN AND ANALOGUES, PRODUCT: OXYTOCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 16:12:14
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 May 2021 16:12:14
Data point term sent to Coder	System	03 May 2021 14:50:01
User entered 'oxytocin'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:49:12
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'pregnancy post-partum'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '20/1000'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	03 May 2021 14:49:12
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'units/mL'	Kelsey Kelley (b) (4)	03 May 2021 14:49:12
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 14:49:12
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:49:12
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 14:49:12
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:49:12
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:49:12

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:49:12

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:49:12

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:49:12

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 15:14:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 15:14:13
Data point term sent to Coder	System	03 May 2021 14:51:02
User entered 'Clindamycin'	Kelsey Kelley (b) (4)	03 May 2021 14:50:34



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:50:34
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '900'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 14:50:34
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'four times daily (QID)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	03 May 2021 14:51:34
	(b) (4)	
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	03 May 2021 14:50:34
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34



US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '28 Apr 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:50:34
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 May 2021 14:51:34
User entered '1'	System	03 May 2021 14:50:34

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 14:50:34



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 14:50:34

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 14:53:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 14:53:13
Data point term sent to Coder	System	03 May 2021 14:52:02
User entered 'lactated ringers'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '1000'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mL (mL)'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:51:27



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:51:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:51:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:51:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:51:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:51:27



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:51:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:51:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:51:27

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:59

Name of Medication

Audit	User		Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: OTHER GYNECOLOGICALS, ATC: SYMPATHOMIMETICS, LABOUR REPRESSANTS, PRODUCT: TERBUTALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	03 May 2021 16:17:39
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 May 2021 16:17:39
User signature succeeded.	Keith Vrbicky (b) (4)	(b) (4)	03 May 2021 16:17:32
Data point term sent to Coder	System		03 May 2021 14:54:04
User entered 'Terbutaline'	Kelsey Kelley (b) (4)	(b) (4)	03 May 2021 14:53:39

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0.25'	(b) (4) Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:53:39

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:53:39

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:53:39

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:53:39

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:53:39

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:53:39
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:53:39

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:53:39

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:53:39

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:53:39

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 15:58:22
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 May 2021 15:58:22
Data point term sent to Coder	System	03 May 2021 14:55:04
User entered 'Lidocaine 1%'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:54:37
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:54:37
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '20'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mL (mL)'	Kelsey Kelley (b) (4)	03 May 2021 14:54:37
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	03 May 2021 14:54:37
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'Epidural'	Kelsey Kelley (b) (4)	03 May 2021 14:54:37
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:54:37
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:54:37
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:54:37

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:54:37

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: MORPHINAN DERIVATIVES, PRODUCT: BUTORPHANOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 15:13:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 15:13:13
Data point term sent to Coder	System	03 May 2021 14:56:05
User entered 'butorphanol'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '1'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:55:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:55:27

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:55:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:55:27



US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	03 May 2021 14:55:27
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:55:27

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:55:27



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:55:27

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: UTEROTONICS, ATC: PROSTAGLANDINS, PRODUCT: CARBOPROST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 15:14:14
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 May 2021 15:14:14
Data point term sent to Coder	System	03 May 2021 14:57:05
User entered 'carboprost'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:56:14
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '250'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'ug (ug)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:47:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14



US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '28 Apr 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:56:14
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:14



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:56:14

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:56:14

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 15:59:42
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 May 2021 15:59:42
Data point term sent to Coder	System	03 May 2021 14:57:06
User entered 'Loperamide'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:41

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '2'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	



US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:41

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:41

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:41

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:41



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:56:41
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:56:41

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:56:41

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:56:41

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:56:41

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4) Coder Import (b) (4)	03 May 2021 15:57:22
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 May 2021 15:57:22
Data point term sent to Coder	System	03 May 2021 14:58:07
User entered 'Fentanyl'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:47:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 14:57:28
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:57:28
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '50'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'ug (ug)'	Kelsey Kelley (b) (4)	03 May 2021 14:57:28
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 14:57:28
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	03 May 2021 14:57:28
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Epidural'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '28 Apr 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:57:28
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:57:28

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:57:28

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 15:59:43
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 May 2021 15:59:43
Data point term sent to Coder	System	03 May 2021 14:59:08
User entered 'metoclopramide'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 14:58:22
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '10'	Kelsey Kelley (b) (4)	03 May 2021 14:58:22
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 14:58:22
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22



US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:58:22
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:47:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 14:58:22
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 14:58:22

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:58:22

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:58:22



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 14:58:22

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: UTEROTONICS, ATC: PROSTAGLANDINS, PRODUCT: MISOPROSTOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 16:12:14
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 May 2021 16:12:14
Data point term sent to Coder	System	03 May 2021 15:02:10
User entered 'misoprostol'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:01:31

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:47:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '800'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'ug (ug)'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:01:31



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:01:31

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'intravaginal'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:01:31

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:01:31
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:01:31



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:01:31

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:01:31

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:01:31

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: OXYTOCIN AND ANALOGUES, PRODUCT: OXYTOCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 16:12:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 16:12:14
Data point term sent to Coder	System	03 May 2021 15:04:19
User entered 'oxytocin'	Kelsey Kelley (b) (4)	03 May 2021 15:03:18

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 15:03:18
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '30'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	03 May 2021 15:03:18
	(b) (4)	



US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'units'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:03:18
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:03:18
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:18

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:18

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:18

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:18

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ALKA-SELTZER - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 16:12:14
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 May 2021 16:12:14
Data point term sent to Coder	System	03 May 2021 15:04:13
User entered 'alka-seltzer'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 15:03:57
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 15:03:57
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '2'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'tablet (TABLET)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 15:03:57
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 15:03:57
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:03:57
	(b) (4)	



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 15:03:57
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:03:57
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:57

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:57

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID, PRODUCTSYNONYM: TRANEXAMIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 16:22:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 16:22:17
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	03 May 2021 16:17:32
Data point term sent to Coder	System	03 May 2021 15:05:23
User entered 'Tranexamic'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 15:05:11
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 15:05:11
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '1000'	(b) (4) Kelsey Kelley (b) (4)	03 May 2021 15:05:11
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 15:05:11
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:47:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 15:05:11
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '28 Apr 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 15:05:11
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:05:11
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:05:11

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:05:11

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:05:11



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:05:11

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 16:14:16
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 May 2021 16:14:16
Data point term sent to Coder	System	03 May 2021 15:07:32
User entered 'nicotine'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:06:25

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'smoking cessation'	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '21'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:06:25

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:06:25



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:06:25

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'Topical (TOPICAL)'	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:47:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:06:25

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:06:25
	(b) (4)	

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:06:25



**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 15:06:25

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 15:06:25

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 15:06:25

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 May 2021 15:57:22
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 May 2021 15:57:22
Data point term sent to Coder	System	03 May 2021 15:07:32
User entered 'Ephedrine sulfate'	Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 15:07:08
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'labor and delivery'	Kelsey Kelley (b) (4)	03 May 2021 15:07:08
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	03 May 2021 15:07:08
	(b) (4)	



US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

US3032112

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	03 May 2021 15:07:08
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered '28 Apr 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '0'	Kelsey Kelley (b) (4)	03 May 2021 15:07:08
	(b) (4)	

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	03 May 2021 15:07:08
	(b) (4)	



US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
	(b) (4)	
User entered '28 Apr 2021'	Kelsey Kelley (b) (4)	03 May 2021 15:07:08
	(b) (4)	

US3032112

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:47:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	03 May 2021 16:17:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	03 May 2021 15:07:08

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:07:08

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:07:08

**US3032112**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:47:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:07:08

US3032112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:47:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:08:59
DataPoint Verified.		07 Apr 2021 22:03:34
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:53:52
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:53:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 13:31:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 13:30:57
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 13:21:43
	(b) (4)	

US3032112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:03:40
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered '31 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:54:08
	(b) (4)	

US3032112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:03:40
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'ultrasound'	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:54:08
	(b) (4)	



US3032112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:03:40
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:54:08

US3032112

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:59

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:03:40
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	08 Mar 2021 22:54:08
	(b) (4)	

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'USA-US032-2021-MRNA-1273-P301000007'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20



**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Keith'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Vrbicky'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:58
User entered 'US'	System	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 18:36:36
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
	(b) (4)	
User entered '2'	System	11 Feb 2021 20:43:11
User entered '1'	System	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'USA-US032-2021-MRNA-1273-P301000007'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20



**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Keith'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Vrbicky'	System	11 Feb 2021 18:41:20



**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:58
User entered 'US'	System	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 18:36:36
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
	(b) (4)	
User entered '2'	System	11 Feb 2021 20:43:11
User entered '1'	System	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:47:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '11/Feb/2021 13:41'	(b) (4) System	11 Feb 2021 18:41:48

US3032112

Folder: SAE USA-US032-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:59

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:58
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'USA-US032-2021-MRNA-1273-P301000007'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20



**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Keith'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Vrbicky'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:58
User entered 'US'	System	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 18:36:36
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
	(b) (4)	
User entered '2'	System	11 Feb 2021 20:43:11
User entered '1'	System	11 Feb 2021 18:41:48



**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:47:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered '11/Feb/2021 20:43'	(b) (4) System	11 Feb 2021 20:43:11

US3032112

Folder: SAE USA-US032-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:59

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:36:55
DataPoint Verified.		23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:11

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'USA-US032-2021-MRNA-1273-P301000007'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20



**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Yes (Y)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'No (N)'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Keith'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:41:41
User entered 'Vrbicky'	System	11 Feb 2021 18:41:20

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 16:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:58
User entered 'US'	System	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:47:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 18:36:36
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:30
	(b) (4)	
User entered '2'	System	11 Feb 2021 20:43:11
User entered '1'	System	11 Feb 2021 18:41:48

**US3032112**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:47:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:18
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:20
User entered '16/Apr/2021 14:36'	(b) (4) System	16 Apr 2021 18:36:36

US3032112

Folder: SAE USA-US032-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:59

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:20
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:36:55
User entered '1'		16 Apr 2021 18:36:36