

US3222017 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:03:55

All time stamps listed in this document are displayed in GMT

US3222017

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

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[Participant ID](#)

US3222017

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

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US3222017

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

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

Visit date (dd MMM yyyy)	06 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3222017

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Date of Informed Consent ( <i>dd MMM yyyy</i> )	6 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 16:27:32

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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) 16 Feb 2021 16:27:32

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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) 16 Feb 2021 16:27:32

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Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	01 JAN 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 16:27:32

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Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	10 JAN 2010
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)	10 JAN 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Condition	NON-ALCOHOLIC FATTY LIVER DISEASE
Start date (dd MMM yyyy)	01 APR 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)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2010
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3222017

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Condition	CHOLCYSTECTOMY
Start date (dd MMM yyyy)	01 JAN 2010
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)	01 JAN 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Condition	ENDARTERECTOMY
Start date (dd MMM yyyy)	10 JAN 2011
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)	10 JAN 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Feb 2021 16:27:32

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Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	01 JAN 2009
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)	01 JAN 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:27:32

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	06 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:30 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 15:30
Height ( <i>xxx.x</i> )	162.5 cm
Weight ( <i>xxx.x</i> )	104.3 kg
BMI ( <i>xxx.x</i> )	39.49822 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) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 16:27:32

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Date of assessment (dd MMM yyyy) 06 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 True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 16:27:32

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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** RETIRED

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 16:27:32

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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)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 184983

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) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

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) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

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)	6 AUG 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 15:30
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG



US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

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)	06 AUG 2020
Time of assessment (00:00-23:59)	16:36 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:36
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG

US3222017

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 AUG 2020

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

US3222017

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 16:01 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 16:01

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) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	6 AUG 2020
Collection time ( <i>00:00-23:59</i> )	15:50 (24 HR)
Collection date and time (derived)	6 AUG 2020 15:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:52	6 AUG 2020 15:52
Nasopharyngeal Swab 2	Yes	15:52	6 AUG 2020 15:52

US3222017

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**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

98.8 °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 16:42

PC Open Date & Time

06 AUG 2020 16:21

PC Close Date & Time

06 AUG 2020 18:51

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 AUG 2020 19:46

PC Close Date & Time

07 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**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

97.8 °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 20:36

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**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

98.2 °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

08 AUG 2020 12:09

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**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

97.8 °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 AUG 2020 20:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**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

98.2 °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

10 AUG 2020 20:09

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

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

11 AUG 2020 16:53

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**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

12 AUG 2020 17:29

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**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

06 AUG 2020 16:42

PC Open Date & Time

06 AUG 2020 16:21

PC Close Date & Time

06 AUG 2020 18:51

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 AUG 2020 19:46

PC Close Date & Time

07 AUG 2020 11:59



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**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

07 AUG 2020 20:37

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**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

08 AUG 2020 12:09

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**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

09 AUG 2020 20:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**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

10 AUG 2020 20:10

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**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

11 AUG 2020 16:54

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**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

12 AUG 2020 17:29

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**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 ☐

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 16:43
PC Open Date & Time	06 AUG 2020 16:21
PC Close Date & Time	06 AUG 2020 18:51



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**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 ☐

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 19:46

PC Close Date & Time

07 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**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 ☒

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 20:38
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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 ☒

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:10
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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 ☒

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EAB) (1725)

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:21
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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 ☒

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 16:55
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

60 of 1361

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 17:30
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3222017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:31

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:31

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:31

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

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)	3 SEP 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 15:05
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

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)	3 SEP 2020
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 16:35
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3222017

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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



US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 15:45 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 15:45

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

US3222017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	16:00 (24 HR)
Collection date and time (derived)	3 SEP 2020 16:00

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:30	3 SEP 2020 16:30
Nasopharyngeal Swab 2	No		

US3222017

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:21

PC Open Date & Time

03 SEP 2020 16:05

PC Close Date & Time

03 SEP 2020 18:35

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**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 98.1 °F

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

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

PC Time Stamp	04 SEP 2020 09:15
PC Open Date & Time	03 SEP 2020 19:30
PC Close Date & Time	04 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**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

97.8 °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

04 SEP 2020 20:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 14:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**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

97.8 °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 SEP 2020 12:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °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

07 SEP 2020 12:01

---

PC Open Date & Time

07 SEP 2020 12:00

---

PC Close Date & Time

08 SEP 2020 11:59

---

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**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

98.2 °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

08 SEP 2020 19:10

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:17

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 16:22

PC Open Date & Time

03 SEP 2020 16:05

PC Close Date & Time

03 SEP 2020 18:35

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**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 09:16

PC Open Date & Time

03 SEP 2020 19:30

PC Close Date & Time

04 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**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 20:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**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 14:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**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 12:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**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 12:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**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

08 SEP 2020 19:10

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**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 18:17

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**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 ☐

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 16:22
PC Open Date & Time	03 SEP 2020 16:05
PC Close Date & Time	03 SEP 2020 18:35

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**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 ☐

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 09:17
PC Open Date & Time	03 SEP 2020 19:30
PC Close Date & Time	04 SEP 2020 11:59



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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)

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 14:51
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**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 ☒

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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 ☒

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:01
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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 ☒

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:11
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

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EAB) (1725)

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:18
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3222017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:31

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:31

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 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

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

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) \_\_\_\_\_

US3222017

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

1 OCT 2020

---

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

---

US3222017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	15:17 (24 HR)
Collection date and time (derived)	1 OCT 2020 15:17

US3222017

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:49:53

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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



**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 NOV 2020 11:54:39
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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 07:25:47
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**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

17 NOV 2020 08:07:17

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**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

28 NOV 2020 09:06:56

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**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 12:09:36

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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 17:56:44
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**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

19 DEC 2020 22:11:23

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**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

26 DEC 2020 09:34:13

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**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

02 JAN 2021 07:51:41

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

<b>TIMEPOINT</b>	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 22:05:57
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 10:48:07
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 08:01:25

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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 <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"/>

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**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

07 FEB 2021 12:56:32

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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	13 FEB 2021 11:49:40
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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	20 FEB 2021 08:39:23
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59



US3222017

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 16:03:55**

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

US3222017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:32

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222017

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:31

Generated On: 09 Jun 2021 16:03:55

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*



US3222017

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:31

Generated On: 09 Jun 2021 16:03:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3222017**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:03:55**

Was this visit performed? Yes ☐  
No ☐

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

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

Folder OID \_\_\_\_\_

US3222017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

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

US3222017

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

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.*

US3222017

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

**US3222017**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:03:55**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222017

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:03:55

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"/>

**US3222017**

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

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

**Generated On: 09 Jun 2021 16:03:55**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3222017

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

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

Visit date (dd MMM yyyy)	28 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3222017

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

Date of updated informed consent (*dd MMM yyyy*) 28 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 28 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3222017

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

11:55 (24 HR)

Collection date and time (derived)

28 JAN 2021 11:55

US3222017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	11:58
Collection Date and Time (derived)	28 JAN 2021 11:58

US3222017

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

AEID	USA-US104-2021-MRNA-1273-P30 1000011
Adverse event	CARDIAC ARREST
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 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)	04 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
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"/>

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EAB) (1725)

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US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input checked="" type="radio"/> Not Recovered/Not Resolved <input 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	

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

---

SUBJECT PASSED AWAY LAST  
WEEK. WAS NOTIFIED OF  
DEATH ON 24-FEB-2021 AT  
14:00. WAS NOTIFIED BY  
HUSBAND WHO WILL BE AT  
ACCEL TOMORROW. WILL  
OBTAIN MORE INFORMATION  
THEN.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

---

---



US3222017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

---

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

Yes ☐

No ☒

---

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

---

US3222017

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 16:27:30

Generated On: 09 Jun 2021 16:03:55

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3222017

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 05 Mar 2021 21:32:01

Generated On: 09 Jun 2021 16:03:55

Date of study discontinuation/completion (dd MMM yyyy) 4 FEB 2021

Reason for discontinuation

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

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	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 4 FEB 2021

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

SAEID	USA-US104-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

SAEID	USA-US104-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/FEB/2021 14:55
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

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

SAEID	USA-US104-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/MAR/2021 16:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 13:34:04

Generated On: 09 Jun 2021 16:03:55

SAEID	USA-US104-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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 type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/APR/2021 16:09
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

US3222017 (Prod: Accel Research Site - Avail - ERN-PPDS)



**US3222017**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:03:55**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'US3222017'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:44:22

US3222017

Form: Participant Creation

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	06 Aug 2020 19:57:27

US3222017

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:44:23

US3222017

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	06 Aug 2020 19:57:27

**US3222017**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:03:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'SCRN'	System	06 Aug 2020 19:57:27

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:44:24

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '72'	(b) (4) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:53:03



US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'YEARS'	System	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '72'	System	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Female (F)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Crystal Paccione (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'I'	Crystal Paccione (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Crystal Paccione (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:53:03



US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Crystal Paccione (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Crystal Paccione (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Crystal Paccione (b) (4)	06 Aug 2020 20:53:03

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:12:02
User entered '6 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Aug 2020'	System	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2020'	System	06 Aug 2020 19:57:44



US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:12:05
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:12:08
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:12:12
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:12:27
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:12:25
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 19:57:44

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 17:12:29
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:44:23

US3222017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'I'	System	06 Aug 2020 19:57:51

US3222017

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:03:55

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	06 Aug 2020 19:57:51



US3222017

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:03:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:08:06

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per DM CLR : Please review and verify if CORONARY ARTERY DISEASE and STENT PLACEMENT can be separated and recorded in two different log lines? Reconcile with Con Med eCRF and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:22:11
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:38:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:38:47
Data point term sent to Coder	System	15 Sep 2020 17:38:01
Query 'Per DM CLR : Please review and verify if CORONARY ARTERY DISEASE and STENT PLACEMENT can be separated and recorded in two different log lines? Reconcile with Con Med eCRF and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:37:21
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:37:07
User entered 'CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:37:07
User opened query 'Per DM CLR : Please review and verify if CORONARY ARTERY DISEASE and STENT PLACEMENT can be separated and recorded in two different log lines? Reconcile with Con Med eCRF and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:39:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:02:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:02:09

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	07 Aug 2020 12:09:39
User entered 'CORONARY ARTERY DISEASE WITH STENT PLACEMENT'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:09:38

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Jan 2009' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:10:49
User entered '10 Jan 2009'	Alicia Cevera (b) (4)	07 Aug 2020 12:09:38

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:09:38

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:09:38

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:09:38

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:09:38



US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2009'	System	07 Aug 2020 12:09:38

**US3222017**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:03:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2009'	System	07 Aug 2020 12:09:38

**US3222017**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:03:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	07 Aug 2020 12:09:38

US3222017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	07 Aug 2020 12:09:38

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per DM CLR : Please review and verify if CORONARY ARTERY DISEASE can be removed from this MH term as it is previously recorded in MH #1. Reconcile with Con Med eCRF, update and ensure no duplicate CORONARY ARTERY DISEASE entry will be recorded as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:37:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:39:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:39:53
Data point term sent to Coder	System	15 Sep 2020 17:39:03
Query 'Per DM CLR : Please review and verify if CORONARY ARTERY DISEASE can be removed from this MH term as it is previously recorded in MH #1. Reconcile with Con Med eCRF, update and ensure no duplicate CORONARY ARTERY DISEASE entry will be recorded as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:38:52
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:38:36
User entered 'STENT PLACEMENT' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:38:36
User opened query 'Per DM CLR : Please review and verify if CORONARY ARTERY DISEASE can be removed from this MH term as it is previously recorded in MH #1. Reconcile with Con Med eCRF, update and ensure no duplicate CORONARY ARTERY DISEASE entry will be recorded as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:39:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:02:09

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:02:09
Data point term sent to Coder	System	07 Aug 2020 12:10:40
User entered 'CORONARY ARTERY DISEASE WITH STENT PLACEMENT'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:10:28

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: Coronary Artery Disease and Stent Placement were separated and recorded on different log lines yet the Start and Stop Dates do not match for these conditions. Please review and update if needed.' (Site from DM).	(b) (4)	
Query 'Per CDM: Coronary Artery Disease and Stent Placement were separated and recorded on different log lines yet the Start and Stop Dates do not match for these conditions. Please review and update if needed.' answered with 'CORRECT, THEY DO OT MATCH. CAD BEGAN PRIOR TO STENT PLACEMENT.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:22:53
User opened query 'Per CDM: Coronary Artery Disease and Stent Placement were separated and recorded on different log lines yet the Start and Stop Dates do not match for these conditions. Please review and update if needed.' (Site from DM).	Albert Garcia (b) (4)	12 Oct 2020 14:03:09
User entered '10 Jan 2010'	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 12:41:28
	Alicia Cevera (b) (4)	07 Aug 2020 12:10:28
	(b) (4)	

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:10:28



US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:27:57
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	06 Oct 2020 14:28:01
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	06 Oct 2020 14:27:44
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:39:01
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:10:28

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '10 Jan 2010' reason for change: Data Entry Error	(b) (4)	06 Oct 2020 14:27:44
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:10:28
	(b) (4)	

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:10:28

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2010'	System	07 Aug 2020 12:10:28

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2010'	System	07 Aug 2020 12:10:28

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2010'	System	06 Oct 2020 14:27:44
User entered empty.	System	07 Aug 2020 12:10:28

US3222017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2010'	System	06 Oct 2020 14:27:44
User entered empty.	System	07 Aug 2020 12:10:28

US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Nonalcoholic fatty liver disease, LLT: Non-alcoholic fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 10:41:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 10:41:16
Data point term sent to Coder	System	07 Aug 2020 12:12:40
User entered 'Non-alcoholic fatty liver disease'	Alicia Cevera (b) (4)	07 Aug 2020 12:12:36



US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Apr 2018'	Alicia Cevera (b) (4)	07 Aug 2020 12:12:36

US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:12:36

US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:12:36

US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:12:36

US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:12:36

US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Apr 2018'	System	07 Aug 2020 12:12:36

**US3222017**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:03:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2018'	System	07 Aug 2020 12:12:36

US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	07 Aug 2020 12:12:36



US3222017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	07 Aug 2020 12:12:36

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 12:16:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 12:16:12
Data point term sent to Coder	System	07 Aug 2020 12:14:41
User entered 'Cholecystitis'	Alicia Cevera (b) (4)	07 Aug 2020 12:13:56
	(b) (4)	

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:13:56

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'I'	Alicia Cevera (b) (4)	07 Aug 2020 12:13:56

**US3222017**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:03:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	07 Aug 2020 12:13:56

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Jan 2010'	Alicia Cevera (b) (4)	07 Aug 2020 12:13:56

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:13:56

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	07 Aug 2020 12:13:56



US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	07 Aug 2020 12:13:56

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2010'	System	07 Aug 2020 12:13:56

US3222017

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2010'	System	07 Aug 2020 12:13:56

US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 12:16:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 12:16:13
Data point term sent to Coder	System	07 Aug 2020 12:15:42
User entered 'Cholecystectomy'	Alicia Cevera (b) (4)	07 Aug 2020 12:14:44
	(b) (4)	

US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Jan 2010'	Alicia Cevera (b) (4)	07 Aug 2020 12:14:44

US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:14:44

US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:14:44

US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Jan 2010'	Alicia Cevera (b) (4)	07 Aug 2020 12:14:44



US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:14:44

US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2010'	System	07 Aug 2020 12:14:44

**US3222017**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:03:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2010'	System	07 Aug 2020 12:14:44

US3222017

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2010'	System	07 Aug 2020 12:14:44

**US3222017**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:03:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2010'	System	07 Aug 2020 12:14:44

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Endarterectomy, LLT: Endarterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 12:18:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 12:18:11
Data point term sent to Coder	System	07 Aug 2020 12:17:45
User entered 'Endarterectomy'	Alicia Cevera (b) (4)	07 Aug 2020 12:17:10
	(b) (4)	

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '10 Jan 2011'	Alicia Cevera (b) (4)	07 Aug 2020 12:17:10

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:17:10



US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:17:10

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '10 Jan 2011'	Alicia Cevera (b) (4)	07 Aug 2020 12:17:10

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Alicia Cevera (b) (4)	07 Aug 2020 12:17:10

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2011'	System	07 Aug 2020 12:17:10

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2011'	System	07 Aug 2020 12:17:10

US3222017

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2011'	System	07 Aug 2020 12:17:10

**US3222017**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:03:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2011'	System	07 Aug 2020 12:17:10

US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:54:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:54:14
Data point term sent to Coder	System	27 Aug 2020 19:31:21
User entered 'Postmenopausal'	Amber Vasquez (b) (4)	27 Aug 2020 19:30:47



US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Amber Vasquez (b) (4)	27 Aug 2020 19:30:47

US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'I'	Amber Vasquez (b) (4)	27 Aug 2020 19:30:47

**US3222017**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:03:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	27 Aug 2020 19:30:47

US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Amber Vasquez (b) (4)	27 Aug 2020 19:30:47

US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Amber Vasquez (b) (4)	27 Aug 2020 19:30:47

US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	27 Aug 2020 19:30:47

US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	27 Aug 2020 19:30:47

US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	27 Aug 2020 19:30:47



US3222017

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:03:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered empty.	System	27 Aug 2020 19:30:47

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:40:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:40:55
Data point term sent to Coder	System	15 Sep 2020 17:40:06
User entered 'STENT PLACEMENT'	Albert Garcia (b) (4)	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Jan 2009'	Albert Garcia (b) (4)	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Albert Garcia (b) (4)	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Albert Garcia (b) (4)	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Jan 2009'	Albert Garcia (b) (4)	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Albert Garcia (b) (4)	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2009'	System	15 Sep 2020 17:39:55



US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2009'	System	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'Jan 2009'	System	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:03:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '2009'	System	15 Sep 2020 17:39:55

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '06 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '15:30'	Crystal Paccione (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '06 Aug 2020 15:30'	System	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '162.5' cm	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:55:56
DataPoint set to visible.	(b) (4) System	06 Aug 2020 19:57:51



US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '104.3' kg	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:55:56
DataPoint set to visible.	(b) (4) System	06 Aug 2020 19:57:51

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
Amendment Manager: User entered '39.49822'	System	16 Sep 2020 23:46:16
User entered '39.5'	System	06 Aug 2020 20:55:56
DataPoint set to visible.	System	06 Aug 2020 19:57:51

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'kg/m2'	System	06 Aug 2020 20:55:56
DataPoint set to visible.	System	06 Aug 2020 19:57:51

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:08:36
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:05
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:57:46
User entered '37.1' C	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	15 Sep 2020 17:41:05
User entered 'Oral (Oral)'	(b) (4)	
	Crystal Paccione (b) (4)	06 Aug 2020 20:55:56
	(b) (4)	

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:08:38
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:05
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:57:58
User entered '61'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'bpm'	System	06 Aug 2020 20:55:56



US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:08:41
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:05
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:58:05
User entered '16'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'breaths/min'	System	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:08:43
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:05
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:58:13
User entered '128'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'mmHg'	System	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:08:47
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:05
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:58:19
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 06:59:09
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS PER PI' (Site from System).	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:25:31
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Aug 2020 20:55:56
User entered '102'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'mmHg'	System	06 Aug 2020 20:55:56

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23

US3222017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23



US3222017

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:56:30

US3222017

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
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 10:27:04
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 12:46:55
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:56:30

US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '06 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:57:33

US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	06 Aug 2020 20:57:33

US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:43:17
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'Added to MH' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 19:30:20
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 07:13:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:57:33

US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Crystal Paccione (b) (4)	06 Aug 2020 20:57:33

US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 20:57:33

US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Crystal Paccione (b) (4)	06 Aug 2020 20:57:33



US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Crystal Paccione (b) (4)	06 Aug 2020 20:57:33

US3222017

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:03:55

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'I'	Crystal Paccione (b) (4)	06 Aug 2020 20:57:33

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07



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Folder: Screening

Form: Risk of Exposure

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'RETIRED'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	19 Aug 2020 15:55:52
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	06 Aug 2020 20:58:21
User entered '1' reason for change: Data Entry Error	Crystal Paccione (b) (4)	06 Aug 2020 20:58:21
User entered '0'	(b) (4)	
	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Amber Vasquez (b) (4)	19 Aug 2020 15:55:52
User entered '1'	(b) (4)	
	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07
	(b) (4)	

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '0'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:07

US3222017

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	06 Aug 2020 19:58:08



US3222017

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '6 Aug 2020'	Jennifer Dittman (b) (4)	06 Aug 2020 19:58:08

US3222017

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	06 Aug 2020 19:58:08

**US3222017**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:03:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'VISIT1'	System	06 Aug 2020 19:58:08

US3222017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:44:55

US3222017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:40:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:40:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 19:44:55
User entered '184983' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:44:55

US3222017

Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:44:55

US3222017

Folder: Visit 1 Day 1

Form: Randomization

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Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Alicia Cevera (b) (4)	07 Aug 2020 12:25:28

US3222017

Folder: Visit 1 Day 1

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	07 Aug 2020 12:25:28



US3222017

Folder: Visit 1 Day 1

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Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:25:28

US3222017

Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Alicia Cevera (b) (4)	07 Aug 2020 12:25:28

US3222017

Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:25:28

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:02:26
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 17:41:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:47
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:13
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:13
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:58:46
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:27
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:27
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:11
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:02
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:37:41
User entered '162.5' cm	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:02:28
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 17:41:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:47
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:25
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:25
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:58:54
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:32
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:32
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:19
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:02
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:37:48
User entered '104.3' kg	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:02:26
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 17:41:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:47
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:13
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:13
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:58:46
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:27
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:27
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:11
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:02
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:37:41
User entered '162.5' cm	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:02:28
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 17:41:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:47
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:25
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:25
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:58:54
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:32
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:32
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:19
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:02
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:37:48
User entered '104.3' kg	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User accepted default value 'Pre-Dose (PREDOSE)'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '6 Aug 2020'	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '15:30'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered '6 Aug 2020 15:30'	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:28:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:28:15
User entered '37.1' C reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:28:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:28:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:28:15
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:28:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:28:15
User entered '61' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:28:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:27:25
User entered empty.	System	07 Aug 2020 12:27:25
	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'bpm'	System	07 Aug 2020 12:28:15
User entered empty.	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:28:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:28:15
User entered '16' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:28:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:27:25
User entered empty.	System	07 Aug 2020 12:27:25
	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'breaths/min'	System	07 Aug 2020 12:28:15
User entered empty.	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:28:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:28:15
User entered '128' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:28:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'mmHg'	System	07 Aug 2020 12:28:15
User entered empty.	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Diastolic Blood Pressure reported is out of range > 100 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)	10 Aug 2020 06:59:26
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS PER PI' (Site from System).	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:25:58
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Aug 2020 12:28:15
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:28:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 12:28:15
User entered '102' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:28:15
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'mmHg'	System	07 Aug 2020 12:28:15
User entered empty.	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:02:26
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 17:41:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:47
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:13
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:13
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:58:46
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:27
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:27
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:11
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:02
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:37:41
User entered '162.5' cm	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:02:28
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 17:41:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 17:41:47
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:25
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:41:25
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:58:54
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:32
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:38:32
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:19
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 20:39:02
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:37:48
User entered '104.3' kg	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User accepted default value 'Post-Dose (POSTDOSE)'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '06 Aug 2020'	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
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)	10 Aug 2020 06:59:56
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'confirm correct per protocol' (Site from System).	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:30:10
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).		07 Aug 2020 12:27:25
User entered '16:36'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered '06 Aug 2020 16:36'	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:29:27
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:29:27
User entered '37.1' C reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:29:27
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:27:25
User entered empty.	System	07 Aug 2020 12:27:25
	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 14:26:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 14:26:53
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:29:27
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:29:27
User entered '68' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:29:27
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:27:25
User entered empty.	System	07 Aug 2020 12:27:25
	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'bpm'	System	07 Aug 2020 12:29:27
User entered empty.	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:29:27
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:29:27
User entered '16' reason for change: Data Entry Error	Alicia Cevera (b) (4)	07 Aug 2020 12:29:27
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4)	07 Aug 2020 12:27:25
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'breaths/min'	System	07 Aug 2020 12:29:27
User entered empty.	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)	10 Aug 2020 06:59:59
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS PER PI' (Site from System).	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:26:39
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	07 Aug 2020 12:29:27
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:29:27
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	07 Aug 2020 12:29:27
User entered '159' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:29:27
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'mmHg'	System	07 Aug 2020 12:29:27
User entered empty.	System	07 Aug 2020 12:27:25

US3222017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Diastolic Blood Pressure reported is out of range > 100 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)	10 Aug 2020 07:00:02
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS PER PI' (Site from System).	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:26:41
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Aug 2020 12:29:27
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:29:27
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 12:29:27
User entered '104' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:29:27
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 12:27:25
User entered empty.	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 12:27:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:25
User entered 'mmHg'	System	07 Aug 2020 12:29:27
User entered empty.	System	07 Aug 2020 12:27:25

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:24:40

US3222017

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '6 Aug 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:24:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '6 Aug 2020'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:40



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '16:01'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:40

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '6 Aug 2020 16:01'	System	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Right Arm (RIGHT ARM)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'ONCE'	System	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Exposure

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What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 20:06:40

US3222017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:31

US3222017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '6 Aug 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:31

US3222017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '15:50'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:31



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '6 Aug 2020 15:50'	System	07 Aug 2020 14:27:31

US3222017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '6 Aug 2020'	Alicia Cevera (b) (4)	07 Aug 2020 14:27:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:56

US3222017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '15:52'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:56

US3222017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '6 Aug 2020 15:52'	System	07 Aug 2020 14:27:56

US3222017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:56



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '15:52'	(b) (4) Alicia Cevera (b) (4) (b) (4)	07 Aug 2020 14:27:56

US3222017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered '6 Aug 2020 15:52'	System	07 Aug 2020 14:27:56

US3222017

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	06 Aug 2020 20:06:50

US3222017

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:23
User entered 'I'	System	06 Aug 2020 20:06:50

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:41:40', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ec4e55f7-4ef6-44a4-a714-f5617608e2ed'	System	06 Aug 2020 20:42:12
User entered 'Yes (Y)'	System	06 Aug 2020 20:42:12

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:41:53', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ec4e55f7-4ef6-44a4-a714-f5617608e2ed'	System	06 Aug 2020 20:42:12
User entered '98.8'	System	06 Aug 2020 20:42:12

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:42:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ec4e55f7-4ef6-44a4-a714-f5617608e2ed'	System	06 Aug 2020 20:42:12
User entered 'No (N)'	System	06 Aug 2020 20:42:12



US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:42:10', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ec4e55f7-4ef6-44a4-a714-f5617608e2ed'	System	06 Aug 2020 20:42:12
User entered '06 Aug 2020 16:42'	System	06 Aug 2020 20:42:12

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 16:21'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 18:51'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53



US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 19:46'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 2'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:36:15', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ce144db6-2750-47e9-a854-d84e6c357010'	System	08 Aug 2020 00:39:49
User entered 'Yes (Y)'	System	08 Aug 2020 00:39:49

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:36:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ce144db6-2750-47e9-a854-d84e6c357010'	System	08 Aug 2020 00:39:49
User entered '97.8'	System	08 Aug 2020 00:39:49

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:36:35', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ce144db6-2750-47e9-a854-d84e6c357010'	System	08 Aug 2020 00:39:49
User entered 'No (N)'	System	08 Aug 2020 00:39:49



US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:36:45', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ce144db6-2750-47e9-a854-d84e6c357010'	System	08 Aug 2020 00:39:49
User entered '07 Aug 2020 20:36'	System	08 Aug 2020 00:39:49

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 3'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:03', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '57abde84-02da-4f01-9f45-69c85b8cd6a6'	System	08 Aug 2020 16:09:25
User entered 'Yes (Y)'	System	08 Aug 2020 16:09:25

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:12', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '57abde84-02da-4f01-9f45-69c85b8cd6a6'	System	08 Aug 2020 16:09:25
User entered '98.2'	System	08 Aug 2020 16:09:25

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:17', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '57abde84-02da-4f01-9f45-69c85b8cd6a6'	System	08 Aug 2020 16:09:25
User entered 'No (N)'	System	08 Aug 2020 16:09:25

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:23', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '57abde84-02da-4f01-9f45-69c85b8cd6a6'	System	08 Aug 2020 16:09:25
User entered '08 Aug 2020 12:09'	System	08 Aug 2020 16:09:25



US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 4'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:19:56', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1b11470c-6688-45ae-8144-23971eed0ae6'	System	10 Aug 2020 00:20:22
User entered 'Yes (Y)'	System	10 Aug 2020 00:20:22

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1b11470c-6688-45ae-8144-23971eed0ae6'	System	10 Aug 2020 00:20:22
User entered '97.8'	System	10 Aug 2020 00:20:22

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1b11470c-6688-45ae-8144-23971eed0ae6'	System	10 Aug 2020 00:20:22
User entered 'No (N)'	System	10 Aug 2020 00:20:22

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1b11470c-6688-45ae-8144-23971eed0ae6'	System	10 Aug 2020 00:20:22
User entered '09 Aug 2020 20:20'	System	10 Aug 2020 00:20:22

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 5'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:06:43', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'adc2dea3-c7bb-4bd5-8708-9f3737a9c996'	System	11 Aug 2020 00:09:57
User entered 'Yes (Y)'	System	11 Aug 2020 00:09:57

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:06:52', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'adc2dea3-c7bb-4bd5-8708-9f3737a9c996'	System	11 Aug 2020 00:09:57
User entered '98.2'	System	11 Aug 2020 00:09:57

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:09:47', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'adc2dea3-c7bb-4bd5-8708-9f3737a9c996'	System	11 Aug 2020 00:09:57
User entered 'No (N)'	System	11 Aug 2020 00:09:57

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:09:53', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'adc2dea3-c7bb-4bd5-8708-9f3737a9c996'	System	11 Aug 2020 00:09:57
User entered '10 Aug 2020 20:09'	System	11 Aug 2020 00:09:57

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 6'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:53:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ab358974-ad1d-4918-90b6-31886ac56943'	System	11 Aug 2020 20:54:01
User entered 'Yes (Y)'	System	11 Aug 2020 20:54:01

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:53:46', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ab358974-ad1d-4918-90b6-31886ac56943'	System	11 Aug 2020 20:54:01
User entered '97.8'	System	11 Aug 2020 20:54:01

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:53:51', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ab358974-ad1d-4918-90b6-31886ac56943'	System	11 Aug 2020 20:54:01
User entered 'No (N)'	System	11 Aug 2020 20:54:01

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:53:57', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ab358974-ad1d-4918-90b6-31886ac56943'	System	11 Aug 2020 20:54:01
User entered '11 Aug 2020 16:53'	System	11 Aug 2020 20:54:01

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 7'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a8d5fd03-4d83-4c9d-bab7-012de5e5f280'	System	12 Aug 2020 21:29:29
User entered 'Yes (Y)'	System	12 Aug 2020 21:29:29

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:15', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a8d5fd03-4d83-4c9d-bab7-012de5e5f280'	System	12 Aug 2020 21:29:29
User entered '97.8'	System	12 Aug 2020 21:29:29

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a8d5fd03-4d83-4c9d-bab7-012de5e5f280'	System	12 Aug 2020 21:29:29
User entered 'No (N)'	System	12 Aug 2020 21:29:29

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:26', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a8d5fd03-4d83-4c9d-bab7-012de5e5f280'	System	12 Aug 2020 21:29:29
User entered '12 Aug 2020 17:29'	System	12 Aug 2020 21:29:29

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:42:28', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'c91ace9a-0a3d-4e76-9d7c-7761bf4b999f'	System	06 Aug 2020 20:43:02
User entered 'None (1)'	System	06 Aug 2020 20:43:02



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:42:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'c91ace9a-0a3d-4e76-9d7c-7761bf4b999f'	System	06 Aug 2020 20:43:02
User entered 'No (N)'	System	06 Aug 2020 20:43:02

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:42:45', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'c91ace9a-0a3d-4e76-9d7c-7761bf4b999f'	System	06 Aug 2020 20:43:02
User entered 'No (N)'	System	06 Aug 2020 20:43:02

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:42:54', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'c91ace9a-0a3d-4e76-9d7c-7761bf4b999f'	System	06 Aug 2020 20:43:02
User entered 'None (1)'	System	06 Aug 2020 20:43:02

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:42:59', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'c91ace9a-0a3d-4e76-9d7c-7761bf4b999f'	System	06 Aug 2020 20:43:02
User entered '06 Aug 2020 16:42'	System	06 Aug 2020 20:43:02

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 16:21'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 18:51'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 19:46'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 2'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:37:09', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ba1143ca-62e7-4228-a2b2-267dd650215b'	System	08 Aug 2020 00:39:57
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 00:39:57

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:37:14', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ba1143ca-62e7-4228-a2b2-267dd650215b'	System	08 Aug 2020 00:39:57
User entered 'No (N)'	System	08 Aug 2020 00:39:57

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:37:17', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ba1143ca-62e7-4228-a2b2-267dd650215b'	System	08 Aug 2020 00:39:57
User entered 'No (N)'	System	08 Aug 2020 00:39:57

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:37:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ba1143ca-62e7-4228-a2b2-267dd650215b'	System	08 Aug 2020 00:39:57
User entered 'None (1)'	System	08 Aug 2020 00:39:57

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:37:37', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ba1143ca-62e7-4228-a2b2-267dd650215b'	System	08 Aug 2020 00:39:57
User entered '07 Aug 2020 20:37'	System	08 Aug 2020 00:39:57

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 3'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '24256acd-2a26-47b0-844d-4b8551c5bec8'	System	08 Aug 2020 16:09:50
User entered 'None (1)'	System	08 Aug 2020 16:09:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:33', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '24256acd-2a26-47b0-844d-4b8551c5bec8'	System	08 Aug 2020 16:09:50
User entered 'No (N)'	System	08 Aug 2020 16:09:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:36', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '24256acd-2a26-47b0-844d-4b8551c5bec8'	System	08 Aug 2020 16:09:50
User entered 'No (N)'	System	08 Aug 2020 16:09:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:40', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '24256acd-2a26-47b0-844d-4b8551c5bec8'	System	08 Aug 2020 16:09:50
User entered 'None (1)'	System	08 Aug 2020 16:09:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:48', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '24256acd-2a26-47b0-844d-4b8551c5bec8'	System	08 Aug 2020 16:09:50
User entered '08 Aug 2020 12:09'	System	08 Aug 2020 16:09:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 4'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:26', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '054f4ed9-ac6e-4004-8cef-b3145d88091f'	System	10 Aug 2020 00:20:44
User entered 'None (1)'	System	10 Aug 2020 00:20:44

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '054f4ed9-ac6e-4004-8cef-b3145d88091f'	System	10 Aug 2020 00:20:44
User entered 'No (N)'	System	10 Aug 2020 00:20:44

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '054f4ed9-ac6e-4004-8cef-b3145d88091f'	System	10 Aug 2020 00:20:44
User entered 'No (N)'	System	10 Aug 2020 00:20:44

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:36', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '054f4ed9-ac6e-4004-8cef-b3145d88091f'	System	10 Aug 2020 00:20:44
User entered 'None (1)'	System	10 Aug 2020 00:20:44

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '054f4ed9-ac6e-4004-8cef-b3145d88091f'	System	10 Aug 2020 00:20:44
User entered '09 Aug 2020 20:20'	System	10 Aug 2020 00:20:44

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 5'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:03', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5ca29054-ccbe-4a60-b4e5-4925f489a8bf'	System	11 Aug 2020 00:10:19
User entered 'None (1)'	System	11 Aug 2020 00:10:19

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5ca29054-ccbe-4a60-b4e5-4925f489a8bf'	System	11 Aug 2020 00:10:19
User entered 'No (N)'	System	11 Aug 2020 00:10:19

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:09', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5ca29054-ccbe-4a60-b4e5-4925f489a8bf'	System	11 Aug 2020 00:10:19
User entered 'No (N)'	System	11 Aug 2020 00:10:19

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:12', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5ca29054-ccbe-4a60-b4e5-4925f489a8bf'	System	11 Aug 2020 00:10:19
User entered 'None (1)'	System	11 Aug 2020 00:10:19

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:16', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5ca29054-ccbe-4a60-b4e5-4925f489a8bf'	System	11 Aug 2020 00:10:19
User entered '10 Aug 2020 20:10'	System	11 Aug 2020 00:10:19

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 6'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:08', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1adb8ba0-844e-484b-bcd2-ee628d4c6724'	System	11 Aug 2020 20:54:32
User entered 'None (1)'	System	11 Aug 2020 20:54:32

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:10', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1adb8ba0-844e-484b-bcd2-ee628d4c6724'	System	11 Aug 2020 20:54:32
User entered 'No (N)'	System	11 Aug 2020 20:54:32

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1adb8ba0-844e-484b-bcd2-ee628d4c6724'	System	11 Aug 2020 20:54:32
User entered 'No (N)'	System	11 Aug 2020 20:54:32

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1adb8ba0-844e-484b-bcd2-ee628d4c6724'	System	11 Aug 2020 20:54:32
User entered 'None (1)'	System	11 Aug 2020 20:54:32

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1adb8ba0-844e-484b-bcd2-ee628d4c6724'	System	11 Aug 2020 20:54:32
User entered '11 Aug 2020 16:54'	System	11 Aug 2020 20:54:32

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 7'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f93e9c66-044f-4098-a004-5c12082d1b15'	System	12 Aug 2020 21:29:50
User entered 'None (1)'	System	12 Aug 2020 21:29:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:36', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f93e9c66-044f-4098-a004-5c12082d1b15'	System	12 Aug 2020 21:29:50
User entered 'No (N)'	System	12 Aug 2020 21:29:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f93e9c66-044f-4098-a004-5c12082d1b15'	System	12 Aug 2020 21:29:50
User entered 'No (N)'	System	12 Aug 2020 21:29:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:43', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f93e9c66-044f-4098-a004-5c12082d1b15'	System	12 Aug 2020 21:29:50
User entered 'None (1)'	System	12 Aug 2020 21:29:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:47', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f93e9c66-044f-4098-a004-5c12082d1b15'	System	12 Aug 2020 21:29:50
User entered '12 Aug 2020 17:29'	System	12 Aug 2020 21:29:50

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered 'None (0)'	System	06 Aug 2020 20:43:45

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered 'None (0)'	System	06 Aug 2020 20:43:45

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:23', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered 'None (0)'	System	06 Aug 2020 20:43:45

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:26', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered 'None (0)'	System	06 Aug 2020 20:43:45

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:29', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered 'None (0)'	System	06 Aug 2020 20:43:45

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered 'None (0)'	System	06 Aug 2020 20:43:45

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered 'No (N)'	System	06 Aug 2020 20:43:45



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-06T16:43:43', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'de114d5b-1a2f-4baf-9f16-4c1ab1cc40e0'	System	06 Aug 2020 20:43:45
User entered '06 Aug 2020 16:43'	System	06 Aug 2020 20:43:45

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 16:21'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 18:51'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Aug 2020 19:46'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 2'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:37:46', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered 'None (0)'	System	08 Aug 2020 00:40:01



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:38:00', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered 'None (0)'	System	08 Aug 2020 00:40:01

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:38:04', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered 'None (0)'	System	08 Aug 2020 00:40:01

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:38:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered 'None (0)'	System	08 Aug 2020 00:40:01

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:38:10', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered 'None (0)'	System	08 Aug 2020 00:40:01

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:38:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered 'None (0)'	System	08 Aug 2020 00:40:01

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:38:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered 'No (N)'	System	08 Aug 2020 00:40:01

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-07T20:38:23', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '13af7f19-5b6d-4aa5-899e-b40acd4cd8b5'	System	08 Aug 2020 00:40:01
User entered '07 Aug 2020 20:38'	System	08 Aug 2020 00:40:01

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 3'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:54', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered 'None (0)'	System	08 Aug 2020 16:10:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:09:57', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered 'None (0)'	System	08 Aug 2020 16:10:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:10:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered 'None (0)'	System	08 Aug 2020 16:10:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:10:04', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered 'None (0)'	System	08 Aug 2020 16:10:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:10:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered 'None (0)'	System	08 Aug 2020 16:10:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:10:09', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered 'None (0)'	System	08 Aug 2020 16:10:22



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:10:12', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered 'No (N)'	System	08 Aug 2020 16:10:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-08T12:10:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a0adf214-88b4-4a14-a94f-b38521abbeb4'	System	08 Aug 2020 16:10:22
User entered '08 Aug 2020 12:10'	System	08 Aug 2020 16:10:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 4'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:44', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered 'None (0)'	System	10 Aug 2020 00:21:08

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:48', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered 'None (0)'	System	10 Aug 2020 00:21:08

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:51', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered 'None (0)'	System	10 Aug 2020 00:21:08



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:53', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered 'None (0)'	System	10 Aug 2020 00:21:08

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:56', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered 'None (0)'	System	10 Aug 2020 00:21:08

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:20:58', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered 'None (0)'	System	10 Aug 2020 00:21:08

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:21:02', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered 'No (N)'	System	10 Aug 2020 00:21:08

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-09T20:21:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'd3dda14f-5000-451d-9ae9-1acbb1377fa3'	System	10 Aug 2020 00:21:08
User entered '09 Aug 2020 20:21'	System	10 Aug 2020 00:21:08

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 5'	System	06 Aug 2020 20:06:40



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:22', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered 'None (0)'	System	11 Aug 2020 00:10:44

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:25', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered 'None (0)'	System	11 Aug 2020 00:10:44

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:27', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered 'None (0)'	System	11 Aug 2020 00:10:44

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:29', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered 'None (0)'	System	11 Aug 2020 00:10:44

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered 'None (0)'	System	11 Aug 2020 00:10:44

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:34', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered 'None (0)'	System	11 Aug 2020 00:10:44

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered 'No (N)'	System	11 Aug 2020 00:10:44

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-10T20:10:41', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6c933343-f925-4f3d-81e4-f5d5ba5e31d3'	System	11 Aug 2020 00:10:44
User entered '10 Aug 2020 20:10'	System	11 Aug 2020 00:10:44



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 6'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a'	System	11 Aug 2020 20:55:26
User entered 'None (0)'	System	11 Aug 2020 20:55:26

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:41', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a'	System	11 Aug 2020 20:55:26
User entered 'None (0)'	System	11 Aug 2020 20:55:26

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:47', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a' User entered 'None (0)'	System	11 Aug 2020 20:55:26
	System	11 Aug 2020 20:55:26

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:54:52', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a'	System	11 Aug 2020 20:55:26
User entered 'None (0)'	System	11 Aug 2020 20:55:26

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:55:00', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a'	System	11 Aug 2020 20:55:26
User entered 'None (0)'	System	11 Aug 2020 20:55:26



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:55:03', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a'	System	11 Aug 2020 20:55:26
User entered 'None (0)'	System	11 Aug 2020 20:55:26

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:55:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a'	System	11 Aug 2020 20:55:26
User entered 'No (N)'	System	11 Aug 2020 20:55:26

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-11T16:55:22', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '7e81f844-a16e-4602-9792-445059f5281a'	System	11 Aug 2020 20:55:26
User entered '11 Aug 2020 16:55'	System	11 Aug 2020 20:55:26

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 7'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:53', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered 'None (0)'	System	12 Aug 2020 21:30:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:56', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered 'None (0)'	System	12 Aug 2020 21:30:22



US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:29:58', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered 'None (0)'	System	12 Aug 2020 21:30:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:30:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered 'None (0)'	System	12 Aug 2020 21:30:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:30:04', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered 'None (0)'	System	12 Aug 2020 21:30:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:30:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered 'None (0)'	System	12 Aug 2020 21:30:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:30:11', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered 'No (N)'	System	12 Aug 2020 21:30:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-08-12T17:30:19', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'fe130c63-312a-4f82-a943-6a6c03d418a6'	System	12 Aug 2020 21:30:22
User entered '12 Aug 2020 17:30'	System	12 Aug 2020 21:30:22

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:06:40

US3222017

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	13 Aug 2020 17:50:29

US3222017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '13 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	13 Aug 2020 17:50:29

US3222017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Vasquez (b) (4)	13 Aug 2020 17:50:29

US3222017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Amber Vasquez (b) (4)	13 Aug 2020 17:50:29

US3222017

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	13 Aug 2020 17:50:32

US3222017

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User entered 'I'	System	13 Aug 2020 17:50:32

US3222017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	04 Sep 2020 13:32:27

US3222017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '20 Aug 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	04 Sep 2020 13:32:27



US3222017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Albert Garcia (b) (4)	04 Sep 2020 13:32:27

US3222017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) Albert Garcia (b) (4)	04 Sep 2020 13:32:27

US3222017

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	03 Sep 2020 20:07:12

US3222017

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:46
User entered 'I'	System	03 Sep 2020 20:07:12

US3222017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:07:10
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 13:32:42

US3222017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:07:10
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '27 Aug 2020'	Albert Garcia (b) (4)	04 Sep 2020 13:32:42

US3222017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:07:10
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	04 Sep 2020 13:32:42

US3222017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:07:10
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Albert Garcia (b) (4)	04 Sep 2020 13:32:42



US3222017

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:07:10
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Sep 2020 20:07:47

US3222017

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:07:10
User entered 'I'	System	03 Sep 2020 20:07:47

US3222017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 12:46:55

US3222017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '3 Sep 2020'	Albert Garcia (b) (4)	04 Sep 2020 12:46:55

US3222017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	04 Sep 2020 12:46:55

US3222017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'VISIT2'	System	04 Sep 2020 12:46:55

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25



US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '3 Sep 2020'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '15:05'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '3 Sep 2020 15:05'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '37.0' C	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '69'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'bpm'	System	04 Sep 2020 12:48:25



US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '16'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'breaths/min'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '150'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'mmHg'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '92'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'mmHg'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25



US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '3 Sep 2020'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '16:35'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '3 Sep 2020 16:35'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '36.7' C	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '81'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'bpm'	System	04 Sep 2020 12:48:25



US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '18'	(b) (4) Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'breaths/min'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)	10 Sep 2020 13:44:05
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 12:48:38
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Sep 2020 12:48:25
User entered '156'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'mmHg'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '89'	Albert Garcia (b) (4)	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'mmHg'	System	04 Sep 2020 12:48:25

US3222017

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 12:48:49

US3222017

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '3 Sep 2020'	Albert Garcia (b) (4)	04 Sep 2020 12:48:49



US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Jennifer Dittman (b) (4)	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Jennifer Dittman (b) (4)	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '3 Sep 2020'	Jennifer Dittman (b) (4)	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '15:45'	Jennifer Dittman (b) (4)	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '3 Sep 2020 15:45'	System	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	04 Sep 2020 12:49:11
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	04 Sep 2020 12:49:11
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Albert Garcia (b) (4)	04 Sep 2020 12:49:11
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	03 Sep 2020 20:08:43
User entered 'Left Arm (LEFT ARM)'	System	03 Sep 2020 20:08:43
	Jennifer Dittman (b) (4)	03 Sep 2020 20:08:43
	(b) (4)	



US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'ONCE'	System	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 20:08:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 12:49:29

US3222017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '3 Sep 2020'	Albert Garcia (b) (4)	04 Sep 2020 12:49:29

US3222017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '16:00'	Albert Garcia (b) (4)	04 Sep 2020 12:49:29

US3222017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '3 Sep 2020 16:00'	System	04 Sep 2020 12:49:29

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '3 Sep 2020'	Albert Garcia (b) (4)	04 Sep 2020 12:49:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 12:49:43



US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 12:49:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '16:30'	Albert Garcia (b) (4)	04 Sep 2020 12:49:43

**US3222017**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:03:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '3 Sep 2020 16:30'	System	04 Sep 2020 12:49:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 12:49:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Albert Garcia (b) (4)	04 Sep 2020 12:49:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Albert Garcia (b) (4)	04 Sep 2020 12:49:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered empty.	System	04 Sep 2020 12:49:43

US3222017

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	04 Sep 2020 12:49:47



US3222017

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '1'	System	04 Sep 2020 12:49:47

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:20:59', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bb5f4008-e4bf-4043-be71-1be88647ce67'	System	03 Sep 2020 20:21:22
User entered 'Yes (Y)'	System	03 Sep 2020 20:21:22

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:21:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bb5f4008-e4bf-4043-be71-1be88647ce67'	System	03 Sep 2020 20:21:22
User entered '98.1'	System	03 Sep 2020 20:21:22

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:21:10', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bb5f4008-e4bf-4043-be71-1be88647ce67'	System	03 Sep 2020 20:21:22
User entered 'No (N)'	System	03 Sep 2020 20:21:22

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:21:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bb5f4008-e4bf-4043-be71-1be88647ce67'	System	03 Sep 2020 20:21:22
User entered '03 Sep 2020 16:21'	System	03 Sep 2020 20:21:22

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 16:05'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 18:35'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:15:36', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '268acfa1-2b6f-4e99-a016-547f51a64d46'	System	04 Sep 2020 13:16:00
User entered 'Yes (Y)'	System	04 Sep 2020 13:16:00

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:15:46', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '268acfa1-2b6f-4e99-a016-547f51a64d46'	System	04 Sep 2020 13:16:00
User entered '98.1'	System	04 Sep 2020 13:16:00

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:15:51', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '268acfa1-2b6f-4e99-a016-547f51a64d46'	System	04 Sep 2020 13:16:00
User entered 'No (N)'	System	04 Sep 2020 13:16:00

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:15:57', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '268acfa1-2b6f-4e99-a016-547f51a64d46'	System	04 Sep 2020 13:16:00
User entered '04 Sep 2020 09:15'	System	04 Sep 2020 13:16:00

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 19:30'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 2'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:05', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '919ca5f9-4dc7-490e-ae5e-05f526caed58'	System	05 Sep 2020 00:20:24
User entered 'Yes (Y)'	System	05 Sep 2020 00:20:24

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:12', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '919ca5f9-4dc7-490e-ae5e-05f526caed58'	System	05 Sep 2020 00:20:24
User entered '97.8'	System	05 Sep 2020 00:20:24

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:17', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '919ca5f9-4dc7-490e-ae5e-05f526caed58'	System	05 Sep 2020 00:20:24
User entered 'No (N)'	System	05 Sep 2020 00:20:24

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '919ca5f9-4dc7-490e-ae5e-05f526caed58'	System	05 Sep 2020 00:20:24
User entered '04 Sep 2020 20:20'	System	05 Sep 2020 00:20:24

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 3'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:49:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '70f71346-157c-462f-a781-9221c05a5a2c'	System	05 Sep 2020 18:50:05
User entered 'Yes (Y)'	System	05 Sep 2020 18:50:05



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:49:50', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '70f71346-157c-462f-a781-9221c05a5a2c'	System	05 Sep 2020 18:50:05
User entered '98.6'	System	05 Sep 2020 18:50:05

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:49:54', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '70f71346-157c-462f-a781-9221c05a5a2c'	System	05 Sep 2020 18:50:05
User entered 'No (N)'	System	05 Sep 2020 18:50:05

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '70f71346-157c-462f-a781-9221c05a5a2c'	System	05 Sep 2020 18:50:05
User entered '05 Sep 2020 14:50'	System	05 Sep 2020 18:50:05

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 4'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8348cd1c-23c8-40de-8c62-37ed2aeff1dc'	System	06 Sep 2020 16:02:17
User entered 'Yes (Y)'	System	06 Sep 2020 16:02:17

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:20', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8348cd1c-23c8-40de-8c62-37ed2aeff1dc'	System	06 Sep 2020 16:02:17
User entered '97.8'	System	06 Sep 2020 16:02:17



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:25', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8348cd1c-23c8-40de-8c62-37ed2aeff1dc'	System	06 Sep 2020 16:02:17
User entered 'No (N)'	System	06 Sep 2020 16:02:17

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8348cd1c-23c8-40de-8c62-37ed2aeff1dc'	System	06 Sep 2020 16:02:17
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 16:02:17

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 5'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:00:56', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '383f50cc-8aee-4393-90b4-84fc6c6a9ebd'	System	07 Sep 2020 16:01:41
User entered 'Yes (Y)'	System	07 Sep 2020 16:01:41

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:03', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '383f50cc-8aee-4393-90b4-84fc6c6a9ebd'	System	07 Sep 2020 16:01:41
User entered '98.2'	System	07 Sep 2020 16:01:41

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:09', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '383f50cc-8aee-4393-90b4-84fc6c6a9ebd'	System	07 Sep 2020 16:01:41
User entered 'No (N)'	System	07 Sep 2020 16:01:41



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '383f50cc-8aee-4393-90b4-84fc6c6a9ebd'	System	07 Sep 2020 16:01:41
User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:01:41

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 6'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'b74e051a-7c25-4602-af77-c14bed07d493'	System	08 Sep 2020 23:10:30
User entered 'Yes (Y)'	System	08 Sep 2020 23:10:30

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:17', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'b74e051a-7c25-4602-af77-c14bed07d493'	System	08 Sep 2020 23:10:30
User entered '98.2'	System	08 Sep 2020 23:10:30

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:23', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'b74e051a-7c25-4602-af77-c14bed07d493'	System	08 Sep 2020 23:10:30
User entered 'No (N)'	System	08 Sep 2020 23:10:30

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:26', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'b74e051a-7c25-4602-af77-c14bed07d493'	System	08 Sep 2020 23:10:30
User entered '08 Sep 2020 19:10'	System	08 Sep 2020 23:10:30



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 7'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '3dd7119d-0c48-40f3-a2d9-af129668cc8b'	System	09 Sep 2020 22:17:21
User entered 'Yes (Y)'	System	09 Sep 2020 22:17:21

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:09', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '3dd7119d-0c48-40f3-a2d9-af129668cc8b' User entered '98.2'	System	09 Sep 2020 22:17:21
	System	09 Sep 2020 22:17:21

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '3dd7119d-0c48-40f3-a2d9-af129668cc8b'	System	09 Sep 2020 22:17:21
User entered 'No (N)'	System	09 Sep 2020 22:17:21

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:16', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '3dd7119d-0c48-40f3-a2d9-af129668cc8b'	System	09 Sep 2020 22:17:21
User entered '09 Sep 2020 18:17'	System	09 Sep 2020 22:17:21

US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:21:28', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f3c9e9d2-00e4-4c9f-8a81-8a1dc161c995'	System	03 Sep 2020 20:22:08
User entered 'None (1)'	System	03 Sep 2020 20:22:08

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:21:35', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f3c9e9d2-00e4-4c9f-8a81-8a1dc161c995'	System	03 Sep 2020 20:22:08
User entered 'No (N)'	System	03 Sep 2020 20:22:08

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:21:44', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f3c9e9d2-00e4-4c9f-8a81-8a1dc161c995'	System	03 Sep 2020 20:22:08
User entered 'No (N)'	System	03 Sep 2020 20:22:08

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:21:56', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f3c9e9d2-00e4-4c9f-8a81-8a1dc161c995'	System	03 Sep 2020 20:22:08
User entered 'None (1)'	System	03 Sep 2020 20:22:08

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'f3c9e9d2-00e4-4c9f-8a81-8a1dc161c995'	System	03 Sep 2020 20:22:08
User entered '03 Sep 2020 16:22'	System	03 Sep 2020 20:22:08

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 16:05'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 18:35'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '2b0ce4a3-bf9a-4a74-9c25-eda3c8191430'	System	04 Sep 2020 13:16:29
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 13:16:29

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:10', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '2b0ce4a3-bf9a-4a74-9c25-eda3c8191430'	System	04 Sep 2020 13:16:29
User entered 'No (N)'	System	04 Sep 2020 13:16:29

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:14', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '2b0ce4a3-bf9a-4a74-9c25-eda3c8191430'	System	04 Sep 2020 13:16:29
User entered 'No (N)'	System	04 Sep 2020 13:16:29

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:17', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '2b0ce4a3-bf9a-4a74-9c25-eda3c8191430'	System	04 Sep 2020 13:16:29
User entered 'None (1)'	System	04 Sep 2020 13:16:29

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:28', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '2b0ce4a3-bf9a-4a74-9c25-eda3c8191430'	System	04 Sep 2020 13:16:29
User entered '04 Sep 2020 09:16'	System	04 Sep 2020 13:16:29

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 19:30'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 2'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:28', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '05a8cc47-82be-4008-bc6c-bd12cc80366b'	System	05 Sep 2020 00:20:48
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 00:20:48

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:31', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '05a8cc47-82be-4008-bc6c-bd12cc80366b'	System	05 Sep 2020 00:20:48
User entered 'No (N)'	System	05 Sep 2020 00:20:48

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '05a8cc47-82be-4008-bc6c-bd12cc80366b'	System	05 Sep 2020 00:20:48
User entered 'No (N)'	System	05 Sep 2020 00:20:48

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:41', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '05a8cc47-82be-4008-bc6c-bd12cc80366b'	System	05 Sep 2020 00:20:48
User entered 'None (1)'	System	05 Sep 2020 00:20:48

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:45', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '05a8cc47-82be-4008-bc6c-bd12cc80366b'	System	05 Sep 2020 00:20:48
User entered '04 Sep 2020 20:20'	System	05 Sep 2020 00:20:48

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 3'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:11', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '07a549ff-3577-458a-966a-7ed4d49dd93b'	System	05 Sep 2020 18:50:31
User entered 'None (1)'	System	05 Sep 2020 18:50:31

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:15', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '07a549ff-3577-458a-966a-7ed4d49dd93b'	System	05 Sep 2020 18:50:31
User entered 'No (N)'	System	05 Sep 2020 18:50:31

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '07a549ff-3577-458a-966a-7ed4d49dd93b'	System	05 Sep 2020 18:50:31
User entered 'No (N)'	System	05 Sep 2020 18:50:31

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:22', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '07a549ff-3577-458a-966a-7ed4d49dd93b'	System	05 Sep 2020 18:50:31
User entered 'None (1)'	System	05 Sep 2020 18:50:31

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:28', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '07a549ff-3577-458a-966a-7ed4d49dd93b'	System	05 Sep 2020 18:50:31
User entered '05 Sep 2020 14:50'	System	05 Sep 2020 18:50:31

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 4'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:36', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '82d30cec-82de-414d-a307-809ef44ab8e0'	System	06 Sep 2020 16:02:43
User entered 'None (1)'	System	06 Sep 2020 16:02:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '82d30cec-82de-414d-a307-809ef44ab8e0'	System	06 Sep 2020 16:02:43
User entered 'No (N)'	System	06 Sep 2020 16:02:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:42', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '82d30cec-82de-414d-a307-809ef44ab8e0'	System	06 Sep 2020 16:02:43
User entered 'No (N)'	System	06 Sep 2020 16:02:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:45', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '82d30cec-82de-414d-a307-809ef44ab8e0'	System	06 Sep 2020 16:02:43
User entered 'None (1)'	System	06 Sep 2020 16:02:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:49', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '82d30cec-82de-414d-a307-809ef44ab8e0'	System	06 Sep 2020 16:02:43
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 16:02:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 5'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86c34c00-18fb-43f8-b283-fff2b8aba0c2'	System	07 Sep 2020 16:02:05
User entered 'None (1)'	System	07 Sep 2020 16:02:05

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86c34c00-18fb-43f8-b283-fff2b8aba0c2'	System	07 Sep 2020 16:02:05
User entered 'No (N)'	System	07 Sep 2020 16:02:05

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:24', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86c34c00-18fb-43f8-b283-fff2b8aba0c2'	System	07 Sep 2020 16:02:05
User entered 'No (N)'	System	07 Sep 2020 16:02:05

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:27', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86c34c00-18fb-43f8-b283-fff2b8aba0c2'	System	07 Sep 2020 16:02:05
User entered 'None (1)'	System	07 Sep 2020 16:02:05

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:31', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86c34c00-18fb-43f8-b283-fff2b8aba0c2'	System	07 Sep 2020 16:02:05
User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:02:05

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 6'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8b81852a-9c3c-4466-8852-2870d0e52d17'	System	08 Sep 2020 23:10:55
User entered 'None (1)'	System	08 Sep 2020 23:10:55

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:42', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8b81852a-9c3c-4466-8852-2870d0e52d17'	System	08 Sep 2020 23:10:55
User entered 'No (N)'	System	08 Sep 2020 23:10:55

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:45', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8b81852a-9c3c-4466-8852-2870d0e52d17'	System	08 Sep 2020 23:10:55
User entered 'No (N)'	System	08 Sep 2020 23:10:55

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:48', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8b81852a-9c3c-4466-8852-2870d0e52d17'	System	08 Sep 2020 23:10:55
User entered 'None (1)'	System	08 Sep 2020 23:10:55

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:51', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8b81852a-9c3c-4466-8852-2870d0e52d17'	System	08 Sep 2020 23:10:55
User entered '08 Sep 2020 19:10'	System	08 Sep 2020 23:10:55

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 7'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:24', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '98a0335b-b111-423a-867a-290e77f4b4c1'	System	09 Sep 2020 22:17:47
User entered 'None (1)'	System	09 Sep 2020 22:17:47

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:27', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '98a0335b-b111-423a-867a-290e77f4b4c1'	System	09 Sep 2020 22:17:47
User entered 'No (N)'	System	09 Sep 2020 22:17:47

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '98a0335b-b111-423a-867a-290e77f4b4c1'	System	09 Sep 2020 22:17:47
User entered 'No (N)'	System	09 Sep 2020 22:17:47

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '98a0335b-b111-423a-867a-290e77f4b4c1'	System	09 Sep 2020 22:17:47
User entered 'None (1)'	System	09 Sep 2020 22:17:47

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:46', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '98a0335b-b111-423a-867a-290e77f4b4c1'	System	09 Sep 2020 22:17:47
User entered '09 Sep 2020 18:17'	System	09 Sep 2020 22:17:47

US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered 'None (0)'	System	03 Sep 2020 20:22:49

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered 'None (0)'	System	03 Sep 2020 20:22:49

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered 'None (0)'	System	03 Sep 2020 20:22:49

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:26', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered 'None (0)'	System	03 Sep 2020 20:22:49

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered 'None (0)'	System	03 Sep 2020 20:22:49

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered 'None (0)'	System	03 Sep 2020 20:22:49



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered 'No (N)'	System	03 Sep 2020 20:22:49

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-03T16:22:47', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'a372cd1d-d634-4407-b54e-e39be7b13a38'	System	03 Sep 2020 20:22:49
User entered '03 Sep 2020 16:22'	System	03 Sep 2020 20:22:49

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 16:05'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 18:35'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:34', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered 'None (0)'	System	04 Sep 2020 13:17:06

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:41', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered 'No interference with activity (1)'	System	04 Sep 2020 13:17:06

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:45', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered 'None (0)'	System	04 Sep 2020 13:17:06



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:48', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered 'None (0)'	System	04 Sep 2020 13:17:06

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:51', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered 'None (0)'	System	04 Sep 2020 13:17:06

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:54', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered 'None (0)'	System	04 Sep 2020 13:17:06

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:16:59', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered 'No (N)'	System	04 Sep 2020 13:17:06

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T09:17:05', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '563d1cb6-be1d-40c8-98a8-6cf0d38b30b6'	System	04 Sep 2020 13:17:06
User entered '04 Sep 2020 09:17'	System	04 Sep 2020 13:17:06

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '03 Sep 2020 19:30'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 2'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:20:57', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered 'No interference with activity (1)'	System	05 Sep 2020 00:21:39

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:21:00', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered 'No interference with activity (1)'	System	05 Sep 2020 00:21:39

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:21:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered 'None (0)'	System	05 Sep 2020 00:21:39

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:21:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered 'None (0)'	System	05 Sep 2020 00:21:39

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:21:20', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered 'None (0)'	System	05 Sep 2020 00:21:39

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:21:23', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered 'None (0)'	System	05 Sep 2020 00:21:39

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:21:27', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered 'No (N)'	System	05 Sep 2020 00:21:39

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-04T20:21:37', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '86f45d8e-9acd-4258-894b-6250cc348e86'	System	05 Sep 2020 00:21:39
User entered '04 Sep 2020 20:21'	System	05 Sep 2020 00:21:39



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 3'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered 'None (0)'	System	05 Sep 2020 18:51:53

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:47', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered 'Some interference with activity (2)'	System	05 Sep 2020 18:51:53

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:55', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered 'None (0)'	System	05 Sep 2020 18:51:53

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:50:58', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered 'None (0)'	System	05 Sep 2020 18:51:53

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:51:16', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	05 Sep 2020 18:51:53



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:51:24', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered 'Some interference with activity not requiring medical attention (2)'	System	05 Sep 2020 18:51:53

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:51:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered 'No (N)'	System	05 Sep 2020 18:51:53

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-05T14:51:50', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '87403b77-a5db-4b14-ab88-aaab245744f3'	System	05 Sep 2020 18:51:53
User entered '05 Sep 2020 14:51'	System	05 Sep 2020 18:51:53

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 4'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:01:54', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered 'None (0)'	System	06 Sep 2020 16:03:12

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:02:00', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered 'None (0)'	System	06 Sep 2020 16:03:12



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:02:03', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered 'None (0)'	System	06 Sep 2020 16:03:12

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:02:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered 'None (0)'	System	06 Sep 2020 16:03:12

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:02:09', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered 'None (0)'	System	06 Sep 2020 16:03:12

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:02:11', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered 'None (0)'	System	06 Sep 2020 16:03:12

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:02:16', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered 'No (N)'	System	06 Sep 2020 16:03:12

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-06T12:02:20', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'eb737a8f-c079-420f-a607-417882be5112'	System	06 Sep 2020 16:03:12
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 16:03:12

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 5'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:35', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered 'None (0)'	System	07 Sep 2020 16:02:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:38', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered 'None (0)'	System	07 Sep 2020 16:02:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:41', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered 'None (0)'	System	07 Sep 2020 16:02:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:43', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered 'None (0)'	System	07 Sep 2020 16:02:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:46', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered 'None (0)'	System	07 Sep 2020 16:02:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:48', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered 'None (0)'	System	07 Sep 2020 16:02:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:51', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered 'No (N)'	System	07 Sep 2020 16:02:24



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-07T12:01:54', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '72639823-1db0-41be-b153-f14cedd497ed'	System	07 Sep 2020 16:02:24
User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:02:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 6'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:10:58', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered 'None (0)'	System	08 Sep 2020 23:11:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:11:02', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered 'None (0)'	System	08 Sep 2020 23:11:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:11:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered 'None (0)'	System	08 Sep 2020 23:11:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:11:09', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered 'None (0)'	System	08 Sep 2020 23:11:24



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:11:11', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered 'None (0)'	System	08 Sep 2020 23:11:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:11:15', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered 'None (0)'	System	08 Sep 2020 23:11:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:11:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered 'No (N)'	System	08 Sep 2020 23:11:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-08T19:11:21', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'bce5a1a5-fd58-4a9b-98b8-0c7ba01cbdf4'	System	08 Sep 2020 23:11:24
User entered '08 Sep 2020 19:11'	System	08 Sep 2020 23:11:24

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	03 Sep 2020 20:08:43
User entered 'Day 7'	System	03 Sep 2020 20:08:43

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:52', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered 'None (0)'	System	09 Sep 2020 22:18:17



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:55', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered 'None (0)'	System	09 Sep 2020 22:18:17

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:17:58', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered 'None (0)'	System	09 Sep 2020 22:18:17

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:18:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered 'None (0)'	System	09 Sep 2020 22:18:17

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:18:04', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered 'None (0)'	System	09 Sep 2020 22:18:17

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:18:06', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered 'None (0)'	System	09 Sep 2020 22:18:17

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:18:11', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered 'No (N)'	System	09 Sep 2020 22:18:17

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-09-09T18:18:14', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5b128878-fdc1-4dc0-840f-94278415204d'	System	09 Sep 2020 22:18:17
User entered '09 Sep 2020 18:18'	System	09 Sep 2020 22:18:17

US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 20:08:43



US3222017

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:03:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 20:08:43

US3222017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:48:33

US3222017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '12 Sep 2020'	Albert Garcia (b) (4)	02 Oct 2020 16:48:33

US3222017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	02 Oct 2020 16:48:33

US3222017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:48:33

US3222017

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:48:37

US3222017

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'I'	System	02 Oct 2020 16:48:37

US3222017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:49:02



US3222017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '19 Sep 2020'	Albert Garcia (b) (4)	02 Oct 2020 16:49:02

US3222017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Albert Garcia (b) (4)	02 Oct 2020 16:49:02

US3222017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:49:02

US3222017

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:49:05

US3222017

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'I'	System	02 Oct 2020 16:49:05

US3222017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:49:51

US3222017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Oct 2020 09:00:09
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CORRECT AS ENTERED' (Site from System).	Albert Garcia (b) (4) (b) (4)	02 Oct 2020 16:50:04
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Oct 2020 16:49:51
User entered '28 Sep 2020'	Albert Garcia (b) (4) (b) (4)	02 Oct 2020 16:49:51

US3222017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	02 Oct 2020 16:49:51



US3222017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:49:51

US3222017

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:50:10

US3222017

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'I'	System	02 Oct 2020 16:50:10

US3222017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 06:48:02
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:49:58
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:11:11
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	02 Oct 2020 16:50:23

US3222017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '1 Oct 2020'	Albert Garcia (b) (4)	02 Oct 2020 16:50:23

US3222017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	02 Oct 2020 16:50:23

US3222017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'VISIT3'	System	02 Oct 2020 16:50:23

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'No (N)'	Albert Garcia (b) (4)	02 Oct 2020 16:50:29



US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered empty.	System	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered empty.	System	02 Oct 2020 16:50:29



US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered empty.	System	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered empty.	System	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered empty.	Albert Garcia (b) (4)	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered empty.	System	02 Oct 2020 16:50:29

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03

US3222017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03



US3222017

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:50:43

US3222017

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '1 Oct 2020'	Albert Garcia (b) (4)	02 Oct 2020 16:50:43

US3222017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Oct 2020 15:50:15

US3222017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '1 Oct 2020'	Albert Garcia (b) (4)	21 Oct 2020 15:50:15

US3222017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered '15:17'	Albert Garcia (b) (4)	21 Oct 2020 15:50:15

US3222017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '1 Oct 2020 15:17'	System	21 Oct 2020 15:50:15

US3222017

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:49:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	02 Oct 2020 16:51:36

US3222017

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered '1'	System	02 Oct 2020 16:51:36



US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 64'	System	06 Aug 2020 20:06:40

US3222017

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[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)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 71'	System	06 Aug 2020 20:06:40

US3222017

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[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)	29 Apr 2021 08:02:52
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
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US3222017

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
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**US3222017**

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

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**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
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**US3222017**

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[Date and time of submission](#)

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US3222017

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 20:06:40

**US3222017**

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

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 78'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	29 Apr 2021 08:02:52
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US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)	29 Apr 2021 08:02:52
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US3222017

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
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US3222017

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:03:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



US3222017

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:03:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:03:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29



US3222017

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:07:29
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 92'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-03T11:54:24', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '9e85d913-8a84-4f1e-a451-dd713f65a6b6'	System	03 Nov 2020 16:54:43
User entered 'No (N)'	System	03 Nov 2020 16:54:43

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-03T11:54:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '9e85d913-8a84-4f1e-a451-dd713f65a6b6'	System	03 Nov 2020 16:54:43
User entered 'No (N)'	System	03 Nov 2020 16:54:43

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-03T11:54:39', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '9e85d913-8a84-4f1e-a451-dd713f65a6b6'	System	03 Nov 2020 16:54:43
User entered '03 Nov 2020 11:54:39'	System	03 Nov 2020 16:54:43



US3222017

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 99'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-10T07:25:36', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '661c5f4c-c1fa-429f-9b6a-451bee8ea108'	System	10 Nov 2020 12:25:52
User entered 'No (N)'	System	10 Nov 2020 12:25:52

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-10T07:25:40', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '661c5f4c-c1fa-429f-9b6a-451bee8ea108'	System	10 Nov 2020 12:25:52
User entered 'No (N)'	System	10 Nov 2020 12:25:52

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-10T07:25:47', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '661c5f4c-c1fa-429f-9b6a-451bee8ea108'	System	10 Nov 2020 12:25:52
User entered '10 Nov 2020 07:25:47'	System	10 Nov 2020 12:25:52

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 20:06:40



US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered 'Day 106'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-17T08:07:10', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ec33b0f1-5a04-471b-b1fd-f92a13643c17'	System	17 Nov 2020 13:07:22
User entered 'No (N)'	System	17 Nov 2020 13:07:22

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-17T08:07:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ec33b0f1-5a04-471b-b1fd-f92a13643c17'	System	17 Nov 2020 13:07:22
User entered 'No (N)'	System	17 Nov 2020 13:07:22

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-17T08:07:17', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'ec33b0f1-5a04-471b-b1fd-f92a13643c17'	System	17 Nov 2020 13:07:22
User entered '17 Nov 2020 08:07:17'	System	17 Nov 2020 13:07:22

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 20:06:40

US3222017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:40:53
Data entry locked.	System	06 Aug 2020 20:06:40
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 20:06:40

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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)	02 May 2021 13:44:27



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27



**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-28T09:06:47', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '92681fa6-b021-4cc4-a31e-13d518cbf33e'	System	28 Nov 2020 14:07:01
User entered 'No (N)'	System	28 Nov 2020 14:07:01

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-28T09:06:51', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '92681fa6-b021-4cc4-a31e-13d518cbf33e'	System	28 Nov 2020 14:07:01
User entered 'No (N)'	System	28 Nov 2020 14:07:01

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-11-28T09:06:56', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '92681fa6-b021-4cc4-a31e-13d518cbf33e'	System	28 Nov 2020 14:07:01
User entered '28 Nov 2020 09:06:56'	System	28 Nov 2020 14:07:01

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:07:29



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-05T12:09:29', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '568ec1b1-dc75-4a89-bb79-48f5a174434a'	System	05 Dec 2020 17:09:42
User entered 'No (N)'	System	05 Dec 2020 17:09:42

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-05T12:09:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '568ec1b1-dc75-4a89-bb79-48f5a174434a'	System	05 Dec 2020 17:09:42
User entered 'No (N)'	System	05 Dec 2020 17:09:42

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-05T12:09:36', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '568ec1b1-dc75-4a89-bb79-48f5a174434a' User entered '05 Dec 2020 12:09:36'	System	05 Dec 2020 17:09:42
	System	05 Dec 2020 17:09:42

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-12T17:56:37', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '00bf74f2-4350-4993-823f-c5a94a90e12b'	System	12 Dec 2020 22:56:49
User entered 'No (N)'	System	12 Dec 2020 22:56:49



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-12T17:56:40', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '00bf74f2-4350-4993-823f-c5a94a90e12b'	System	12 Dec 2020 22:56:49
User entered 'No (N)'	System	12 Dec 2020 22:56:49

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-12T17:56:44', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '00bf74f2-4350-4993-823f-c5a94a90e12b'	System	12 Dec 2020 22:56:49
User entered '12 Dec 2020 17:56:44'	System	12 Dec 2020 22:56:49

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-19T22:11:14', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8f53ee33-3c52-40fb-9c2b-998291d559bf'	System	20 Dec 2020 03:11:29
User entered 'No (N)'	System	20 Dec 2020 03:11:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-19T22:11:17', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8f53ee33-3c52-40fb-9c2b-998291d559bf'	System	20 Dec 2020 03:11:29
User entered 'No (N)'	System	20 Dec 2020 03:11:29

**US3222017**

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

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**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-19T22:11:23', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '8f53ee33-3c52-40fb-9c2b-998291d559bf'	System	20 Dec 2020 03:11:29
User entered '19 Dec 2020 22:11:23'	System	20 Dec 2020 03:11:29



**US3222017**

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

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-26T09:34:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '250d8fea-905e-4f3d-aed2-04b0f0fbc9a3'	System	26 Dec 2020 14:34:16
User entered 'No (N)'	System	26 Dec 2020 14:34:16

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-26T09:34:03', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '250d8fea-905e-4f3d-aed2-04b0f0fbc9a3'	System	26 Dec 2020 14:34:16
User entered 'No (N)'	System	26 Dec 2020 14:34:16

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2020-12-26T09:34:13', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '250d8fea-905e-4f3d-aed2-04b0f0fbc9a3'	System	26 Dec 2020 14:34:16
User entered '26 Dec 2020 09:34:13'	System	26 Dec 2020 14:34:16

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:07:29



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-02T07:51:30', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '747ef9fa-2790-48dd-a68a-11ac00fa0fcf'	System	02 Jan 2021 12:51:47
User entered 'No (N)'	System	02 Jan 2021 12:51:47

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-02T07:51:33', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '747ef9fa-2790-48dd-a68a-11ac00fa0fcf'	System	02 Jan 2021 12:51:47
User entered 'No (N)'	System	02 Jan 2021 12:51:47

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-02T07:51:41', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '747ef9fa-2790-48dd-a68a-11ac00fa0fcf'	System	02 Jan 2021 12:51:47
User entered '02 Jan 2021 07:51:41'	System	02 Jan 2021 12:51:47

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-10T22:05:50', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'b81696d5-f385-44bd-af15-9bac00f3f436'	System	11 Jan 2021 03:06:00
User entered 'No (N)'	System	11 Jan 2021 03:06:00



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-10T22:05:52', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'b81696d5-f385-44bd-af15-9bac00f3f436'	System	11 Jan 2021 03:06:00
User entered 'No (N)'	System	11 Jan 2021 03:06:00

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-10T22:05:57', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: 'b81696d5-f385-44bd-af15-9bac00f3f436'	System	11 Jan 2021 03:06:00
User entered '10 Jan 2021 22:05:57'	System	11 Jan 2021 03:06:00

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-19T10:48:01', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5fd6b7f7-a81f-455e-b43c-197438e53044'	System	19 Jan 2021 15:48:12
User entered 'No (N)'	System	19 Jan 2021 15:48:12

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-19T10:48:03', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5fd6b7f7-a81f-455e-b43c-197438e53044'	System	19 Jan 2021 15:48:12
User entered 'No (N)'	System	19 Jan 2021 15:48:12

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-19T10:48:07', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5fd6b7f7-a81f-455e-b43c-197438e53044'	System	19 Jan 2021 15:48:12
User entered '19 Jan 2021 10:48:07'	System	19 Jan 2021 15:48:12



**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-23T08:01:18', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '22c9e6a9-2a80-4c6e-909f-a56763c94100'	System	23 Jan 2021 13:01:30
User entered 'No (N)'	System	23 Jan 2021 13:01:30

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-23T08:01:22', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '22c9e6a9-2a80-4c6e-909f-a56763c94100'	System	23 Jan 2021 13:01:30
User entered 'No (N)'	System	23 Jan 2021 13:01:30

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-01-23T08:01:25', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '22c9e6a9-2a80-4c6e-909f-a56763c94100'	System	23 Jan 2021 13:01:30
User entered '23 Jan 2021 08:01:25'	System	23 Jan 2021 13:01:30

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:07:29



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27



**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-07T12:56:26', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6eb6200c-58cd-4651-8e83-cb1a16e8f563'	System	07 Feb 2021 17:56:37
User entered 'No (N)'	System	07 Feb 2021 17:56:37

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-07T12:56:29', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6eb6200c-58cd-4651-8e83-cb1a16e8f563'	System	07 Feb 2021 17:56:37
User entered 'No (N)'	System	07 Feb 2021 17:56:37

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-07T12:56:32', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '6eb6200c-58cd-4651-8e83-cb1a16e8f563'	System	07 Feb 2021 17:56:37
User entered '07 Feb 2021 12:56:32'	System	07 Feb 2021 17:56:37



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-13T11:49:31', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5e2fbf9a-ae9b-42c5-80f0-e57b07cc59e5'	System	13 Feb 2021 16:49:44
User entered 'No (N)'	System	13 Feb 2021 16:49:44

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-13T11:49:35', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5e2fbf9a-ae9b-42c5-80f0-e57b07cc59e5'	System	13 Feb 2021 16:49:44
User entered 'No (N)'	System	13 Feb 2021 16:49:44

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-13T11:49:40', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '5e2fbf9a-ae9b-42c5-80f0-e57b07cc59e5'	System	13 Feb 2021 16:49:44
User entered '13 Feb 2021 11:49:40'	System	13 Feb 2021 16:49:44

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:07:29



US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:07:29

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-20T08:39:16', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1c0d46ae-aea4-40f5-8c78-619b80f5a228'	System	20 Feb 2021 16:06:38
User entered 'No (N)'	System	20 Feb 2021 16:06:38

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

Have you been exposed to someone with 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)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-20T08:39:19', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1c0d46ae-aea4-40f5-8c78-619b80f5a228'	System	20 Feb 2021 16:06:38
User entered 'No (N)'	System	20 Feb 2021 16:06:38

US3222017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c250c08b7f480c3)', Time: '2021-02-20T08:39:23', User OID: 'PatientReportedOutcome (US3222017)', ODM File OID: '1c0d46ae-aea4-40f5-8c78-619b80f5a228'	System	20 Feb 2021 16:06:38
User entered '20 Feb 2021 08:39:23'	System	20 Feb 2021 16:06:38

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:07:29

**US3222017**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:03:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:07:29
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:07:29

US3222017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	17 Nov 2020 22:06:08

US3222017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '28 Oct 2020'	Alicia Cevera (b) (4)	17 Nov 2020 22:06:08



US3222017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	17 Nov 2020 22:06:08

US3222017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	Alicia Cevera (b) (4)	17 Nov 2020 22:06:08

US3222017

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	17 Nov 2020 22:06:14

US3222017

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:03:03
User entered 'I'	System	17 Nov 2020 22:06:14

US3222017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	22 Dec 2020 15:42:25

US3222017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '02 Dec 2020'	(b) (4) gail lavine (b) (4) (b) (4)	22 Dec 2020 15:42:25

US3222017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) gail lavine (b) (4) (b) (4)	22 Dec 2020 15:42:25

US3222017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	22 Dec 2020 15:42:25



US3222017

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	22 Dec 2020 15:42:43

US3222017

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User entered 'I'	System	22 Dec 2020 15:42:43

US3222017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 21:15:33

US3222017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 21:15:33

US3222017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 21:15:33

US3222017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 21:15:33

US3222017

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 21:15:38

US3222017

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User entered 'I'	System	30 Dec 2020 21:15:38



US3222017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:41:29

US3222017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:41:29

US3222017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:41:29

US3222017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:41:29

US3222017

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:41:31

US3222017

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:26:53
User entered 'I'	System	01 Feb 2021 19:41:31

US3222017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:19:50

US3222017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:19:50



US3222017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:19:50

US3222017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 20:19:50

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:22:33

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	05 Apr 2021 20:10:19
User entered '0'	(b) (4) douglas winter (b) (4)	01 Apr 2021 15:01:05
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:12:11

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:22:33

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
User closed query 'Per CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4)	09 Apr 2021 10:57:51
Query 'Per CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:47:34
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:47:18
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:47:18
User opened query 'Per CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:14:10
User signature succeeded.	Bruce Rankin (b) (4)	05 Apr 2021 20:10:19
User entered 'Amendment 5 (Amendment 5)'	(b) (4)	01 Apr 2021 15:01:05
Amendment Manager inserted this DataPoint.	douglas winter (b) (4)	06 Mar 2021 03:12:11
	(b) (4)	
	System	

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:22:33

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:22:33



US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:22:33

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:22:33

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:22:33

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered empty.	System	28 Jan 2021 20:22:33

US3222017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered empty.	System	28 Jan 2021 20:22:33

US3222017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:23:07

US3222017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:23:07

US3222017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '11:55'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:23:07



US3222017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered '28 Jan 2021 11:55'	System	28 Jan 2021 20:23:07

US3222017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:23:25

US3222017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:23:25

US3222017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered '11:58'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:23:25

**US3222017**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:03:55**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:06
User entered '28 Jan 2021 11:58'	System	28 Jan 2021 20:23:25

US3222017

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:03:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:33:00
Signature has been broken.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 23:53:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 23:53:13
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 13:38:31
	(b) (4)	

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
Reviewed for Safety.	System	08 Apr 2021 20:08:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:56:08
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered	System	25 Feb 2021 19:55:00
'USA-US104-2021-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	25 Feb 2021 19:55:00

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Bruce Rankin (b) (4)	25 Mar 2021 17:10:58
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardiac arrest, LLT: Cardiac arrest - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 19:46:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 19:46:57
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 19:46:08
Coding entries removed.	Albert Garcia (b) (4)	05 Mar 2021 19:45:41
	(b) (4)	
Signature has been broken.	Albert Garcia (b) (4)	05 Mar 2021 19:45:41
	(b) (4)	
User entered 'CARDIAC ARREST' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Mar 2021 19:45:41
	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Death - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 00:06:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 00:06:04
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 00:05:19
User entered 'Death'	(b) (4), (b) (6)	25 Feb 2021 00:04:33



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
User entered 'No (N)'	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Bruce Rankin (b) (4)	25 Mar 2021 17:10:58
	(b) (4)	
User closed query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Mar 2021 13:46:12
Signature has been broken.	Amber Vasquez (b) (4)	06 Mar 2021 13:46:12
	(b) (4)	
User entered '04 Feb 2021' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Mar 2021 13:46:12
	(b) (4)	
User opened query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	05 Mar 2021 19:49:07
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '17 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
User entered empty.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User entered empty.	System	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
	Bruce Rankin (b) (4)	25 Mar 2021 17:10:58
	(b) (4)	
User closed query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	06 Mar 2021 13:46:12
Signature has been broken.	Amber Vasquez (b) (4)	06 Mar 2021 13:46:12
	(b) (4)	
User entered '04 Feb 2021' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Mar 2021 13:46:12
	(b) (4)	
User opened query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	05 Mar 2021 19:48:33
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 00:05:06
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	25 Feb 2021 00:05:06
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 00:05:06
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 00:05:06
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 00:04:33
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 00:04:33
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 00:04:33



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
User entered empty.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User entered empty.	System	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:32:44
Query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so. ' answered with 'UNKNOWN' (Site from Safety).	Albert Garcia (b) (4)	05 Mar 2021 19:32:56
	(b) (4)	
User opened query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:43:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
User entered empty.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 00:04:33



US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
User entered empty.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 00:04:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:10:58
	(b) (4)	
User closed query 'PV Urgent Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:32:41
Query 'PV Urgent Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	05 Mar 2021 19:33:25
	(b) (4)	
Signature has been broken.	Albert Garcia (b) (4)	05 Mar 2021 19:32:18
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Mar 2021 19:32:18
	(b) (4)	
User opened query 'PV Urgent Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:43:04
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:10:58
	(b) (4)	
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:32:39
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	05 Mar 2021 19:33:47
	(b) (4)	
Signature has been broken.	Albert Garcia (b) (4)	05 Mar 2021 19:32:18
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Mar 2021 19:32:18
	(b) (4)	
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:44:12
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33



US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
User closed query 'Source indicates this is None. Please confirm and or revise if necessary.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 21:30:21
Query 'Source indicates this is None. Please confirm and or revise if necessary.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:46:28
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:46:06
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:46:06
User opened query 'Source indicates this is None. Please confirm and or revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 17:56:34
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 17:56:14
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:56:08
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
User signature succeeded.	(b) (4), (b) (6)	
User entered 'I'	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 00:04:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered 'Fatal (FATAL)'	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:56:08
	(b) (4), (b) (6)	
User closed query '. PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:32:36
User closed query '. PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:32:33
Query '. PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	05 Mar 2021 19:45:22
	(b) (4)	
Query '. PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' answered with 'CARDIAC ARREST' (Site from Safety).	Albert Garcia (b) (4)	05 Mar 2021 19:45:12
	(b) (4)	
User opened query '. PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:43:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query '. PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information, please state so. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	04 Mar 2021 19:43:12
	Vicki Miller (b) (4)	26 Feb 2021 21:33:00
User entered 'Subject passed away last week. Was notified of death on 24-Feb-2021 at 14:00. Was notified by husband who will be at Accel tomorrow. Will obtain more information then.'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 00:04:33



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User entered 'I'	System	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User entered '0'	System	25 Feb 2021 00:04:33

US3222017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27

US3222017

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 16:03:55**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Alicia Cevera (b) (4)	07 Aug 2020 14:29:22

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:03:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:27:33
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 13:36:32

US3222017

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:03:55

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:23:23
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:32:01
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	(b) (4) System	05 Mar 2021 19:49:07
User entered '4 Feb 2021' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Mar 2021 19:49:07
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	05 Mar 2021 19:48:33
User entered '24 Feb 2021'	Albert Garcia (b) (4) (b) (4)	05 Mar 2021 19:48:33

US3222017

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:03:55

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:23:23
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:32:01
User entered 'Death (DEATH)'	Albert Garcia (b) (4)	05 Mar 2021 19:48:33

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:03:55

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:23:23
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:32:01
User entered empty.	Albert Garcia (b) (4)	05 Mar 2021 19:48:33



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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:23:23
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:32:01
User entered 'Adverse event (ADVERSE EVENT)'	Albert Garcia (b) (4)	05 Mar 2021 19:48:33

US3222017

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:23:23
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:32:01
User entered empty.	Albert Garcia (b) (4)	05 Mar 2021 19:48:33

US3222017

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:03:55

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:23:23
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:32:01
User entered '4 Feb 2021'	(b) (4) Albert Garcia (b) (4) (b) (4)	05 Mar 2021 19:48:33

US3222017

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:23:23
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:32:01
User entered 'No (N)'	Albert Garcia (b) (4)	05 Mar 2021 19:48:33

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
Reviewed for Safety.	System	08 Apr 2021 20:08:36
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:31
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:57:32
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4)	25 Feb 2021 19:55:24
User entered 'USA-US104-2021-MRNA-1273-P301000011'	(b) (4), (b) (6)	
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:33
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:35
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:36
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00



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Folder: SAE USA-US104-2021-MRNA-1273-P301000011

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:37
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

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Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:38
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:40
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:41
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

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Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:41
User closed query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:30:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Query 'Please change to Dr. Rankin.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:51:01
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User opened query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 17:58:01
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Teresa'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Becker'	System	25 Feb 2021 19:55:00

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Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:44
Un-reviewed for Safety.	System	08 Apr 2021 20:09:19
User entered '860 Peachwood Ave'	System	08 Apr 2021 20:09:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '860 Peachwood Drive' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '6550 Mapleridge Street'	System	25 Feb 2021 19:55:00

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Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Houston'	System	25 Feb 2021 19:55:00



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 13:50:40

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '77081'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	09 Apr 2021 21:30:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:32:52
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'US'	(b) (4)	25 Feb 2021 19:55:41

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User entered '3'	System	08 Apr 2021 20:09:19
User entered '2'	System	08 Mar 2021 16:33:00
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
	(b) (4)	
User entered '1'	System	25 Feb 2021 19:55:41

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
Reviewed for Safety.	System	08 Apr 2021 20:08:36
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:31
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:57:32
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4)	25 Feb 2021 19:55:24
User entered 'USA-US104-2021-MRNA-1273-P301000011'	(b) (4), (b) (6)	
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:33
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:35
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:36
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'No (N)'	System	25 Feb 2021 19:55:00



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:37
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:38
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:40
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:41
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:41
User closed query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:30:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Query 'Please change to Dr. Rankin.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:51:01
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User opened query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 17:58:01
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Teresa'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Becker'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:44
Un-reviewed for Safety.	System	08 Apr 2021 20:09:19
User entered '860 Peachwood Ave'	System	08 Apr 2021 20:09:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '860 Peachwood Drive' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '6550 Mapleridge Street'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Houston'	System	25 Feb 2021 19:55:00



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 13:50:40

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '77081'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	09 Apr 2021 21:30:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:32:52
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'US'	(b) (4)	25 Feb 2021 19:55:41

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User entered '3'	System	08 Apr 2021 20:09:19
User entered '2'	System	08 Mar 2021 16:33:00
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered '1'	(b) (4)	25 Feb 2021 19:55:41
	System	

**US3222017**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:03:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:45
User signature succeeded.	(b) (4), (b) (6)	
User entered '25/Feb/2021 14:55'	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
	(b) (4)	
	System	25 Feb 2021 19:55:41

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:03:55

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:32:52
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'I'	(b) (4)	25 Feb 2021 19:55:41
	(b) (4), (b) (6)	

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
Reviewed for Safety.	System	08 Apr 2021 20:08:36
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:31
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:57:32
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4)	25 Feb 2021 19:55:24
User entered 'USA-US104-2021-MRNA-1273-P301000011'	(b) (4), (b) (6)	
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:33
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:35
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:36
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:37
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:38
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:40
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:41
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:41
User closed query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:30:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Query 'Please change to Dr. Rankin.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:51:01
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User opened query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 17:58:01
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Teresa'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Becker'	System	25 Feb 2021 19:55:00



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:44
Un-reviewed for Safety.	System	08 Apr 2021 20:09:19
User entered '860 Peachwood Ave'	System	08 Apr 2021 20:09:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '860 Peachwood Drive' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '6550 Mapleridge Street'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Houston'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 13:50:40

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '77081'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	09 Apr 2021 21:30:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:32:52
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'US'	(b) (4)	25 Feb 2021 19:55:41

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User entered '3'	System	08 Apr 2021 20:09:19
User entered '2'	System	08 Mar 2021 16:33:00
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
	(b) (4)	
User entered '1'	System	25 Feb 2021 19:55:41

**US3222017**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:03:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:57:47
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:10:58
User entered '08/Mar/2021 16:32'	(b) (4) System	08 Mar 2021 16:33:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:03:55

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:57:47
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:10:58
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 16:33:00



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
Reviewed for Safety.	System	08 Apr 2021 20:08:36
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:31
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 17:57:32
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4)	25 Feb 2021 19:55:24
User entered 'USA-US104-2021-MRNA-1273-P301000011'	(b) (4), (b) (6)	
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:33
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:35
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:36
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:37
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:38
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:40
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	02 Apr 2021 17:57:41
User signature succeeded.	(b) (4), (b) (6)	
Reviewed for Safety.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:55:24
	System	25 Feb 2021 19:55:00



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:41
User closed query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:30:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Query 'Please change to Dr. Rankin.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:51:01
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User opened query 'Please change to Dr. Rankin.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 17:58:01
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Teresa'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:43
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Becker'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:44
Un-reviewed for Safety.	System	08 Apr 2021 20:09:19
User entered '860 Peachwood Ave'	System	08 Apr 2021 20:09:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '860 Peachwood Drive' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '6550 Mapleridge Street'	System	25 Feb 2021 19:55:00

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Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered 'Houston'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 13:50:40

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:30:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 20:08:24
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:55:24
User entered '77081'	System	25 Feb 2021 19:55:00

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
DataPoint Verified.	System	09 Apr 2021 21:30:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:32:52
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
User entered 'US'	(b) (4)	25 Feb 2021 19:55:41

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User entered '3'	System	08 Apr 2021 20:09:19
User entered '2'	System	08 Mar 2021 16:33:00
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:34:00
	(b) (4)	
User entered '1'	System	25 Feb 2021 19:55:41



US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:03:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
User entered '08/Apr/2021 16:09'	(b) (4) System	08 Apr 2021 20:09:19

US3222017

Folder: SAE USA-US104-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:03:55

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:09:19