

US3332033 (Prod: Foothill Family Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:09:26

All time stamps listed in this document are displayed in GMT

US3332033

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

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[Participant ID](#)

US3332033

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

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US3332033

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3332033

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
Sex	Female <input type="radio"/> Male <input checked="" 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

US3332033

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 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

US3332033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3332033

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

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Were any significant conditions reported?

Yes ☒

No ☐

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US3332033

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	



US3332033

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3332033

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3332033

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	29 SEP 2016
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)	29 SEP 2016
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2016
Start Year (derived)	2016
Stop Month and Year (derived)	SEP 2016
Stop Year (derived)	2016

US3332033

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3332033

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3332033

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

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

US3332033

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	CARDIAC STENT PLACEMENT
Start date (dd MMM yyyy)	29 SEP 2016
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)	29 SEP 2016
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2016
Start Year (derived)	2016
Stop Month and Year (derived)	SEP 2016
Stop Year (derived)	2016

US3332033

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3332033

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:42 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 08:42
Height ( <i>xxx.x</i> )	69.0 in
Weight ( <i>xxx.x</i> )	187.3 lb
BMI ( <i>xxx.x</i> )	27.71721 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)	

US3332033

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3332033

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

US3332033

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

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

US3332033

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185031

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 ☒

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Height	ND - Not Done
Weight	ND - Not Done

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

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)	10 AUG 2020
Time of assessment (00:00-23:59)	08:42 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 08:42
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

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)	10 AUG 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:50
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3332033

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

10 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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US3332033

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 10:06 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 10:06

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

US3332033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	10 AUG 2020
Collection time ( <i>00:00-23:59</i> )	09:09 (24 HR)
Collection date and time (derived)	10 AUG 2020 09:09

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	10 AUG 2020 09:12
Nasopharyngeal Swab 2	No		

US3332033

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 10:42

PC Open Date & Time

10 AUG 2020 10:26

PC Close Date & Time

10 AUG 2020 12:56

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	10 AUG 2020 15:48
PC Open Date & Time	10 AUG 2020 13:51
PC Close Date & Time	11 AUG 2020 11:59



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 15:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**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

96.6 °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

12 AUG 2020 14:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:25

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

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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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 13:13

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

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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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 16:05

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 14:28

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**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

10 AUG 2020 10:43

PC Open Date & Time

10 AUG 2020 10:26

PC Close Date & Time

10 AUG 2020 12:56

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**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

10 AUG 2020 15:48

PC Open Date & Time

10 AUG 2020 13:51

PC Close Date & Time

11 AUG 2020 11:59



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**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

11 AUG 2020 16:00

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**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

12 AUG 2020 14:46

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**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

13 AUG 2020 12:25

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**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

14 AUG 2020 13:14

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**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

15 AUG 2020 16:05

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**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

16 AUG 2020 14:28

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**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 ☐

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 10:44
PC Open Date & Time	10 AUG 2020 10:26
PC Close Date & Time	10 AUG 2020 12:56



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**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 ☐

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 15:49
PC Open Date & Time	10 AUG 2020 13:51
PC Close Date & Time	11 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**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

50 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

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

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 14:46
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:26
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 13:15
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

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)

58 of 2689

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 16:06
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:29
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3332033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

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*

US3332033

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3332033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

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*

US3332033

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

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)	11 SEP 2020
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 08:06
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:44
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3332033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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



US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 09:08 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 09:08

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

US3332033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

08:31 (24 HR)

Collection date and time (derived)

11 SEP 2020 08:31

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:28	11 SEP 2020 08:28
Nasopharyngeal Swab 2	No		

US3332033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 09:41

PC Open Date & Time

11 SEP 2020 09:28

PC Close Date & Time

11 SEP 2020 11:58

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**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	11 SEP 2020 13:33
PC Open Date & Time	11 SEP 2020 12:53
PC Close Date & Time	12 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**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

100.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:42

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

13 SEP 2020 23:24

---

PC Open Date & Time

13 SEP 2020 12:00

---

PC Close Date & Time

14 SEP 2020 11:59

---



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

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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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 16:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**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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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

17 SEP 2020 21:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**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

11 SEP 2020 09:41

PC Open Date & Time

11 SEP 2020 09:28

PC Close Date & Time

11 SEP 2020 11:58

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**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

11 SEP 2020 13:33

PC Open Date & Time

11 SEP 2020 12:53

PC Close Date & Time

12 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**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

12 SEP 2020 15:42

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**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

13 SEP 2020 23:25

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**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

14 SEP 2020 20:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**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

15 SEP 2020 16:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**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

16 SEP 2020 20:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**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

17 SEP 2020 21:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**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 ☐

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 09:42
PC Open Date & Time	11 SEP 2020 09:28
PC Close Date & Time	11 SEP 2020 11:58

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**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 ☐

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 13:34
PC Open Date & Time	11 SEP 2020 12:53
PC Close Date & Time	12 SEP 2020 11:59



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**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 ☒

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:43
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 23:25
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:57
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 16:17
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

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

104 of 2689

EAB) (1725)

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:52
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**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)

106 of 2689

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3332033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3332033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:03

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:06

Generated On: 09 Jun 2021 17:09:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:15:06

Generated On: 09 Jun 2021 17:09:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	08:06 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:06
Temperature ( <i>xxx.x</i> )	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	59 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3332033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

08:31 (24 HR)

Collection date and time (derived)

12 OCT 2020 08:31

US3332033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:05

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

<b>TIMEPOINT</b>	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 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 OCT 2020 08:09:37
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59



US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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"/>

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 16:04:10

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 17:39:30

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 08:53:57

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 11:44:29

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 09:33:48

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**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

02 DEC 2020 00:02:42

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 DEC 2020 10:35:43
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 DEC 2020 10:25:39
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**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

23 DEC 2020 12:15:04

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**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

30 DEC 2020 10:21:44

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 09:05:14

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 JAN 2021 13:11:05
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**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

27 JAN 2021 09:34:54

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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 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 FEB 2021 08:11:13
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**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

10 FEB 2021 07:59:48

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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	20 FEB 2021 18:19:05
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 18:33:17

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 MAR 2021 08:30:18
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 14:49:45

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 08:34:53

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 12:00:48

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 12:01:35

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 12:00:52

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 14:57:45

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 06:26:29

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 07:49:35

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59
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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 DEC 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59
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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

09 FEB 2022 00:01

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13 FEB 2022 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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

Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

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**Generated On: 09 Jun 2021 17:09:26**

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59
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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUN 2022 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3332033**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3332033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:09:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 16:54:34

US3332033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3332033

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4



US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 10:46
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3332033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	10:54 (24 HR)
Collection date and time (derived)	30 MAR 2021 10:54

US3332033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3332033

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332033

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3332033**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:26**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3332033

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:26

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"/>

US3332033

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:09:26

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3332033

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

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

Visit date (dd MMM yyyy)	25 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3332033

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

Date of updated informed consent (dd MMM yyyy) 25 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) 25 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 \_\_\_\_\_

US3332033

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00-23:59)	08:50 (24 HR)
Collection date and time (derived)	25 JAN 2021 08:50

US3332033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	08:20
Collection Date and Time (derived)	25 JAN 2021 08:20

US3332033

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID	
Adverse event	WORSENING OF HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	08:06 (24 HR)
AE start date and time (derived)	11 SEP 2020 08:06
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

327 of 2689



US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

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 type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

329 of 2689

EAB) (1725)

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID	USA-US202-2021-MRNA-1273-P30 1000004
Adverse event	SYNCOPE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

331 of 2689

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

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

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

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SAE INITIALLY REPORTED AS  
UTI BUT UPON RECEIPT OF  
MEDICAL RECORDS ON  
25JAN2021, PI CHANGED SAE TO  
SYNCOPE RECORDS INDICATE  
EVENT MAY BE SECONDARY  
TO VIAGRA USE WHICH THE  
SUBJECT NEVER REPORTED  
TAKING BUT DID CONFIRM HE  
HAS TAKEN FOR YEARS.  
SUBJECT SUDDENTLY FAINTED  
WHILE HOME. AMBULANCE  
CALLED AND BP REPORTED  
AROUND "80/40."  
TRANSMITTED TO ER AND  
TREATED FOR UTI WITH IV  
ANTIBIOTICS AND  
DISCHARGED HOME APRX 4  
HOURS LATER ON PO  
ANTIBIOTICS. COVID TESTING  
NOT DONE.

---

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

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US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

334 of 2689

EAB) (1725)

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID	USA-US202-2021-MRNA-1273-P30 1000005
Adverse event	NON-ST ELEVATION ACUTE MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 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)	05 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	27 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	336 of 2689

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT ADMITTED TO HOSPITAL AND STENT PLACEMENT OCCURRED ON 26 FEB 2021 THEN UNDERWENT CABG ON 01 MAR 2021
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
337 of 2689	

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Data signed:** (b) (4) 03 May 2021 14:45:38

**Generated On: 09 Jun 2021 17:09:26**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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0

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID	USA-US202-2021-MRNA-1273-P30 1000005
Adverse event	WORSENING OF CORONARY ARTERY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 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)	5 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	5 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	339 of 2689

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

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SUBJECT INITIALLY  
HOSPITALIZED 2/26/21 WITH MI,  
STENT PLACED BUT SURGICAL  
INTERVENTION WAS  
RECOMMENDED. SUBJECT  
WANTED TO HAVE SURGERY  
IN HOMETOWN SO HE WAS  
DISCHARGED HOME 2/27/21  
WITH A SCHEDULED CARDIAC  
SURGERY SCHEDULED FOR  
3.1.21. SURGERY PERFORMED  
WITHOUT COMPLICATIONS.  
SUBJECT CURRENTLY STILL  
HOSPITALIZED RECOVERING  
WELL. SUBJECT DISCHARGED  
3.5.21, UNABLE TO TRAVEL FOR  
1 MO

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

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US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID	
Adverse event	HIATAL HERNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

342 of 2689

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID	
Adverse event	PULMONARY EFFUSIONS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID	
Adverse event	ANEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

346 of 2689

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

AEID

Adverse event

LOWER EXTREMITY  
PERIPHERAL EDEMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

1 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

348 of 2689

EAB) (1725)

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 03 May 2021 14:45:38

Generated On: 09 Jun 2021 17:09:26

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

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

Yes ☒

No ☐

---

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

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US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

351 of 2689

EAB) (1725)



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

353 of 2689

EAB) (1725)

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

355 of 2689

EAB) (1725)

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

357 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

359 of 2689

EAB) (1725)



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication PREDIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

363 of 2689

EAB) (1725)

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	17 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

365 of 2689

EAB) (1725)

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication CIPRO

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

367 of 2689

EAB) (1725)



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	6 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication TAMSULOSIN

Prophylaxis Yes ☒  
No ☐

Indication UTI PROPHYLAXIS

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

369 of 2689

EAB) (1725)

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication VIAGRA

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

373 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication ROCEPHIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

375 of 2689

EAB) (1725)



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication SYNCOPE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication \_\_\_\_\_

Prophylaxis Yes ☐  
No ☐

Indication \_\_\_\_\_

Dose per administration \_\_\_\_\_

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

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

379 of 2689

EAB) (1725)

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication TIROFIBAN

Prophylaxis Yes ☒  
No ☐

Indication BLOOD CLOT PROPHYLAXIS

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

381 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication \_\_\_\_\_

Prophylaxis Yes ☐  
No ☐

Indication \_\_\_\_\_

Dose per administration \_\_\_\_\_

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication HEPARIN

Prophylaxis Yes ☒  
No ☐

Indication BLOOD CLOT PROPHYLAXIS

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	IV	
	SUB Q	
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication NOREPINEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF CORONARY  
ARTERY DISEASE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication PROTAMINE

Prophylaxis Yes ☒  
No ☐

Indication HEMORRHAGE PROPHYLAXIS

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

389 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF CORONARY  
ARTERY DISEASE

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

391 of 2689



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication SODIUM CHLORIDE 0.45%

Prophylaxis Yes ☒  
No ☐

Indication SURGICAL PROPHYLAXIS

Dose per administration 500

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF CORONARY  
ARTERY DISEASE

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

395 of 2689

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

Name of Medication TOPROL-XL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF CORONARY  
ARTERY DISEASE

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

397 of 2689

EAB) (1725)

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 Apr 2021 00:09:55

Generated On: 09 Jun 2021 17:09:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 00:09:56

Generated On: 09 Jun 2021 17:09:26

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 00:09:56

Generated On: 09 Jun 2021 17:09:26

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 FEB 2021	CARDIAC STENT PLACEMENT	Adverse Event	
01 MAR 2021	CORONARY ARTERY BYPASS GRAFT X 2	Adverse Event	
26 FEB 2021	CHEST X RAY	Adverse Event	
26 FEB 2021	ECHOCARDIOGRAM	Adverse Event	
26 FEB 2021	EKG	Adverse Event	

US3332033

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:09:26

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3332033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:09:26

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/JAN/2021 18:19
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

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	27/JAN/2021 14:48
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

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/JAN/2021 09:00
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

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 13:31:00

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	04/FEB/2021 12:37
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



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/MAR/2021 13:17
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

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/MAR/2021 10:37
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

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/MAR/2021 09:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/MAR/2021 10:10
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

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/MAR/2021 12:01
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

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/MAR/2021 10:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/MAR/2021 12:48
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



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 12 Apr 2021 16:04:03

Generated On: 09 Jun 2021 17:09:26

SAEID	USA-US202-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/APR/2021 08:48
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

US3332033 (Prod: Foothill Family Clinic)

US3332033

Form: Participant Creation

Generated On: 09 Jun 2021 17:09:26

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'US3332033'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:29:40

US3332033

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 16:20:33

US3332033

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:29:41

US3332033

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Clinic (Clinic)'	Sean Hansen (b) (4)	10 Aug 2020 16:20:33

**US3332033**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'SCRN'	System	10 Aug 2020 16:20:33

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered (b) (6) 1943'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:29:42



US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '77'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered 'YEARS'	System	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered '77'	System	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Male (M)'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'I'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13



US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 16:24:13

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered 'Aug 2020'	System	10 Aug 2020 16:25:28



US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered '2020'	System	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Amendment 1 (1)'	Sean Hansen (b) (4)	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 16:25:28

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:29:41

US3332033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered 'I'	System	10 Aug 2020 16:25:35



US3332033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:09:26

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 16:25:35

US3332033

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:09:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:18:58

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:29
Data point term sent to Coder	System	10 Aug 2020 23:26:54
User entered 'Hypercholesterolemia'	Sean Hansen (b) (4)	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:30:37
User entered 'UN UNK 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:30:37
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'un UNK 2017'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:26:18



US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Jan 2016'	System	10 Mar 2021 03:30:37
User entered 'Jan 2017'	System	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:30:37
User entered '2017'	System	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:26:18

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:30
Data point term sent to Coder	System	10 Aug 2020 23:28:57
User entered 'Hypertension'	Sean Hansen (b) (4)	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:30:58
User entered 'UN UNK 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:30:58
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'un UNK 2017'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:28:10



US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Jan 2016'	System	10 Mar 2021 03:30:58
User entered 'Jan 2017'	System	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:30:58
User entered '2017'	System	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:28:10

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 03:33:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 03:33:12
Data point term sent to Coder	System	10 Mar 2021 03:32:24
Coding entries removed.	(b) (4), (b) (6)	10 Mar 2021 03:32:01
Signature has been broken.		10 Mar 2021 03:32:01
User entered 'DIABETES TYPE 2' reason for change: Data Entry Error		10 Mar 2021 03:32:01
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 23:33:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 23:33:19
Data point term sent to Coder	System	10 Aug 2020 23:29:59
User entered 'Pre diabetes'	Sean Hansen (b) (4)	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 03:32:01
User entered 'UN UNK 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:32:01
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'UN UNK 2017'	Sean Hansen (b) (4)	10 Aug 2020 23:29:23



US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Jan 2016'	System	10 Mar 2021 03:32:01
User entered 'Jan 2017'	System	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:32:01
User entered '2017'	System	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:29:23

US3332033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:29:23



US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:30
Data point term sent to Coder	System	10 Aug 2020 23:31:02
User entered 'Myocardial infarction'	Sean Hansen (b) (4)	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:32:26
User entered '29 Sep 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:32:26
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'un UNK 2017'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Aug 2020 23:32:40
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:32:26
User entered '29 Sep 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:32:26
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'un UNK 2017' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:32:40
	(b) (4)	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Sep 2016'	System	10 Mar 2021 03:32:26
User entered 'Jan 2017'	System	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:32:26
User entered '2017'	System	10 Aug 2020 23:30:20



US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Sep 2016'	System	10 Mar 2021 03:32:26
User entered 'Jan 2017'	System	10 Aug 2020 23:32:40
User entered empty.	System	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:32:26
User entered '2017'	System	10 Aug 2020 23:32:40
User entered empty.	System	10 Aug 2020 23:30:20

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:33:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:33:20
Data point term sent to Coder	System	10 Aug 2020 23:32:06
User entered 'Coronary artery disease'	Sean Hansen (b) (4)	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:32:42
User entered 'UN UNK 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:32:42
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'un UNK 2017'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:31:24



US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Jan 2016'	System	10 Mar 2021 03:32:42
User entered 'Jan 2017'	System	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:32:42
User entered '2017'	System	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	10 Aug 2020 23:31:24

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 16:33:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 16:33:11
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 16:17:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 16:17:53
Data point term sent to Coder	System	26 Feb 2021 16:17:15
User entered 'erectile dysfunction'	(b) (4), (b) (6)	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:16:37



US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Jan 2012'	System	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2012'	System	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	26 Feb 2021 16:16:37

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 21:07:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 21:07:09
Data point term sent to Coder	System	26 Feb 2021 21:06:22
User entered 'SHORTNESS OF BREATH INTERMITTENT'	(b) (4), (b) (6)	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered 'UN Jan 2020'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:07



US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Jan 2020'	System	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2020'	System	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	26 Feb 2021 21:06:07

US3332033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	26 Feb 2021 21:06:07



US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
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)	26 Feb 2021 21:22:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 21:22:54
Data point term sent to Coder	System	26 Feb 2021 21:07:23
User entered 'CARDIAC STENT PLACEMENT'	(b) (4), (b) (6)	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:33:12
User entered '29 Sep 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:33:12
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:33:12
User entered '29 Sep 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:33:12
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	05 Mar 2021 23:08:01
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Sep 2016'	System	10 Mar 2021 03:33:12
User entered 'Jan 2017'	System	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:33:12
User entered '2017'	System	26 Feb 2021 21:06:37



US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Sep 2016'	System	10 Mar 2021 03:33:12
User entered 'Jan 2017'	System	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2016'	System	10 Mar 2021 03:33:12
User entered '2017'	System	26 Feb 2021 21:06:37

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 17:06:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 17:06:52
Data point term sent to Coder	System	11 Mar 2021 17:05:59
User entered 'BENIGN PROSTATIC HYPERTROPHY'	(b) (4), (b) (6)	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:05:48



US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'Jan 2012'	System	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '2012'	System	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered empty.	System	11 Mar 2021 17:05:48

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User closed query 'Per CDM: Please confirm if time 08:42 is AM or PM. Thank you.' (Site from DM).	(b) (4)	28 Sep 2020 06:04:57
Query 'Per CDM: Please confirm if time 08:42 is AM or PM. Thank you.' answered with '24 Hour Format. 08:42 AM. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:12:20
User opened query 'Per CDM: Please confirm if time 08:42 is AM or PM. Thank you.' (Site from DM).	Ty Henry (b) (4)	25 Sep 2020 08:13:20
User entered '08:42'	(b) (4)	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered '10 Aug 2020 08:42'	System	10 Aug 2020 23:43:54



US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '69.0' in	(b) (4)	
	Sean Hansen (b) (4)	10 Aug 2020 23:43:54
DataPoint set to visible.	(b) (4)	
	System	10 Aug 2020 16:25:35

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '187.3' lb	(b) (4)	10 Aug 2020 23:43:54
DataPoint set to visible.	Sean Hansen (b) (4)	10 Aug 2020 16:25:35
	(b) (4)	
	System	

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
Amendment Manager: User entered '27.71721'	System	16 Sep 2020 23:49:49
User entered '27.7'	System	10 Aug 2020 23:43:54
DataPoint set to visible.	System	10 Aug 2020 16:25:35

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'kg/m2'	System	10 Aug 2020 23:43:54
DataPoint set to visible.	System	10 Aug 2020 16:25:35

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:05:01
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:11:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:11:04
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:13:05
User entered '98.1' F	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 18:11:04
User entered 'Oral (Oral)'	Sean Hansen (b) (4)	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:11:04
User entered '58'	Sean Hansen (b) (4)	10 Aug 2020 23:43:54
	(b) (4)	



US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'bpm'	System	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:11:04
User entered '16'	Sean Hansen (b) (4)	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'breaths/min'	System	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:11:04
User entered '139'	Ty Henry (b) (4)	10 Aug 2020 23:43:54
	(b) (4)	

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'mmHg'	System	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered missing code ND - Not Done; reason for	(b) (4)	25 Sep 2020 18:11:04
change Data Entry Error	(b) (4)	
User entered '81'	Sean Hansen (b) (4)	10 Aug 2020 23:43:54
	(b) (4)	

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User entered 'mmHg'	System	10 Aug 2020 23:43:54

US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04



US3332033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04

US3332033

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:46:22

US3332033

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
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)	11 Sep 2020 22:03:15
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 15:22:51
User entered '10 Aug 2020'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:46:22

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37



US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:47:37



US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'I'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 23:47:37

US3332033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:22:04
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:47:37



US3332033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 16:26:08

US3332033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 16:26:08

US3332033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Clinic (Clinic)'	Sean Hansen (b) (4)	10 Aug 2020 16:26:08

US3332033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'VISIT1'	System	10 Aug 2020 16:26:08

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:34:50

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:16:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:16:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 15:34:50
User entered '185031' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:34:50

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:34:50

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 16:28:54



US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 16:28:54

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 16:28:54

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 16:28:54

US3332033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 16:28:54

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:05:06
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:15:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:15:08
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:12:48
User entered '69.0' in	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 18:15:08
User entered '187.3' lb	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:05:06
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:15:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:15:08
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:12:48
User entered '69.0' in	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:15:08
User entered '187.3' lb	Sean Hansen (b) (4)	10 Aug 2020 16:36:06
	(b) (4)	



US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User accepted default value 'Pre-Dose (PREDOSE)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '08:42'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '10 Aug 2020 08:42'	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '98.1' F	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Oral (Oral)'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06



US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '58'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'bpm'	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '16'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'breaths/min'	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '139'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '81'	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	10 Aug 2020 16:36:06



US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:05:06
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:15:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 18:15:08
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:12:48
User entered '69.0' in	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	25 Sep 2020 18:15:08
User entered '187.3' lb	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User accepted default value 'Post-Dose (POSTDOSE)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Aug 2020 23:55:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 23:55:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Aug 2020 23:55:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Aug 2020 16:36:06
User entered empty.	System	10 Aug 2020 16:36:06
	Sean Hansen (b) (4)	10 Aug 2020 16:36:06
	(b) (4)	

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06
	(b) (4)	

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 10:05:36
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Correct as is.' (Site from System).	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:55:37
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 23:55:00
User entered '10:50' reason for change: Data Entry Error	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '10 Aug 2020 10:50'	System	10 Aug 2020 23:55:00
User entered empty.	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '96.9' F reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06



US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '57' reason for change: Data Entry Error	(b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06
	(b) (4)	

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'bpm'	System	10 Aug 2020 23:55:00
User entered empty.	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '16' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'breaths/min'	System	10 Aug 2020 23:55:00
User entered empty.	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '138' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	10 Aug 2020 23:55:00
User entered empty.	System	10 Aug 2020 16:36:06



US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '85' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Aug 2020 23:55:00
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	10 Aug 2020 23:55:00
User entered empty.	System	10 Aug 2020 16:36:06

US3332033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:36:17

US3332033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 16:36:17

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 16:37:01



US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10:06'	Sean Hansen (b) (4)	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered '10 Aug 2020 10:06'	System	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Left Arm (LEFT ARM)'	Sean Hansen (b) (4)	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'ONCE'	System	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 16:37:01

US3332033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:52:46

US3332033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 23:52:46



US3332033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '09:09'	Sean Hansen (b) (4)	10 Aug 2020 23:52:46

**US3332033**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:09:26**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered '10 Aug 2020 09:09'	System	10 Aug 2020 23:52:46

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4)	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '09:12'	Sean Hansen (b) (4)	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered '10 Aug 2020 09:12'	System	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:53:25



US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'No (N)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered empty.	System	10 Aug 2020 23:53:25

US3332033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 23:53:32

US3332033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	10 Aug 2020 23:53:32

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:42:20', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6009a18d-2d45-46e9-9d48-ef560c6453da' User entered 'Yes (Y)'	System	10 Aug 2020 16:43:02
	System	10 Aug 2020 16:43:02

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:42:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6009a18d-2d45-46e9-9d48-ef560c6453da' User entered '96.9'	System	10 Aug 2020 16:43:02
	System	10 Aug 2020 16:43:02



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:42:46', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6009a18d-2d45-46e9-9d48-ef560c6453da' User entered 'No (N)'	System	10 Aug 2020 16:43:02
	System	10 Aug 2020 16:43:02

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:42:58', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6009a18d-2d45-46e9-9d48-ef560c6453da' User entered '10 Aug 2020 10:42'	System	10 Aug 2020 16:43:02
	System	10 Aug 2020 16:43:02

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 10:26'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 12:56'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:47:50', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'ae0d4a65-208d-494c-8ee1-fc6008e03391' User entered 'Yes (Y)'	System	10 Aug 2020 21:48:20
	System	10 Aug 2020 21:48:20

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:47:58', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'ae0d4a65-208d-494c-8ee1-fc6008e03391' User entered '97.5'	System	10 Aug 2020 21:48:20
	System	10 Aug 2020 21:48:20

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:03', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'ae0d4a65-208d-494c-8ee1-fc6008e03391'	System	10 Aug 2020 21:48:20
User entered 'No (N)'	System	10 Aug 2020 21:48:20



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:19', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'ae0d4a65-208d-494c-8ee1-fc6008e03391' User entered '10 Aug 2020 15:48'	System	10 Aug 2020 21:48:20
	System	10 Aug 2020 21:48:20

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 13:51'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 2'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T15:59:27', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '2cde5fa1-1ae6-481a-9107-523d3d0d6ddb' User entered 'Yes (Y)'	System	11 Aug 2020 21:59:50
	System	11 Aug 2020 21:59:50

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T15:59:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '2cde5fa1-1ae6-481a-9107-523d3d0d6ddb' User entered '98.3'	System	11 Aug 2020 21:59:50
	System	11 Aug 2020 21:59:50

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T15:59:38', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '2cde5fa1-1ae6-481a-9107-523d3d0d6ddb' User entered 'No (N)'	System	11 Aug 2020 21:59:50
	System	11 Aug 2020 21:59:50

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T15:59:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '2cde5fa1-1ae6-481a-9107-523d3d0d6ddb' User entered '11 Aug 2020 15:59'	System	11 Aug 2020 21:59:50
	System	11 Aug 2020 21:59:50



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 3'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:45:39', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '8bfdcad9-cf45-4bed-85a0-3d71dfa23987' User entered 'Yes (Y)'	System	12 Aug 2020 20:46:00
	System	12 Aug 2020 20:46:00

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:45:46', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '8bfdcad9-cf45-4bed-85a0-3d71dfa23987' User entered '96.6'	System	12 Aug 2020 20:46:00
	System	12 Aug 2020 20:46:00

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:45:52', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '8bfdcad9-cf45-4bed-85a0-3d71dfa23987'	System	12 Aug 2020 20:46:00
User entered 'No (N)'	System	12 Aug 2020 20:46:00

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:45:57', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '8bfdcad9-cf45-4bed-85a0-3d71dfa23987'	System	12 Aug 2020 20:46:00
User entered '12 Aug 2020 14:45'	System	12 Aug 2020 20:46:00

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:37:01



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 4'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:04', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a4188753-2ede-4e10-a68b-f6f9829f8e3b'	System	13 Aug 2020 18:25:26
User entered 'Yes (Y)'	System	13 Aug 2020 18:25:26

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:12', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a4188753-2ede-4e10-a68b-f6f9829f8e3b' User entered '98.4'	System	13 Aug 2020 18:25:26
	System	13 Aug 2020 18:25:26

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:17', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a4188753-2ede-4e10-a68b-f6f9829f8e3b'	System	13 Aug 2020 18:25:26
User entered 'No (N)'	System	13 Aug 2020 18:25:26

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a4188753-2ede-4e10-a68b-f6f9829f8e3b'	System	13 Aug 2020 18:25:26
User entered '13 Aug 2020 12:25'	System	13 Aug 2020 18:25:26

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 16:37:01



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 5'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:13:41', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6e3d9d1b-5218-4832-a6d7-a324e0ad9e2e' User entered 'Yes (Y)'	System	14 Aug 2020 19:14:17
	System	14 Aug 2020 19:14:17

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:13:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6e3d9d1b-5218-4832-a6d7-a324e0ad9e2e' User entered '97.9'	System	14 Aug 2020 19:14:17
	System	14 Aug 2020 19:14:17

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:13:53', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6e3d9d1b-5218-4832-a6d7-a324e0ad9e2e' User entered 'No (N)'	System	14 Aug 2020 19:14:17
	System	14 Aug 2020 19:14:17

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:13:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '6e3d9d1b-5218-4832-a6d7-a324e0ad9e2e' User entered '14 Aug 2020 13:13'	System	14 Aug 2020 19:14:17
	System	14 Aug 2020 19:14:17

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 6'	System	10 Aug 2020 16:37:01



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:18', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a9c8896-33a0-4bd1-88a9-e458c0dd7b51' User entered 'Yes (Y)'	System	15 Aug 2020 22:05:38
	System	15 Aug 2020 22:05:38

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a9c8896-33a0-4bd1-88a9-e458c0dd7b51' User entered '97.7'	System	15 Aug 2020 22:05:38
	System	15 Aug 2020 22:05:38

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a9c8896-33a0-4bd1-88a9-e458c0dd7b51' User entered 'No (N)'	System	15 Aug 2020 22:05:38
	System	15 Aug 2020 22:05:38

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a9c8896-33a0-4bd1-88a9-e458c0dd7b51' User entered '15 Aug 2020 16:05'	System	15 Aug 2020 22:05:38
	System	15 Aug 2020 22:05:38

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 7'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52916cc7-e0e9-452e-8db8-90a9ac0c2cd7' User entered 'Yes (Y)'	System	16 Aug 2020 20:28:16
	System	16 Aug 2020 20:28:16



US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:07', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52916cc7-e0e9-452e-8db8-90a9ac0c2cd7' User entered '97.5'	System	16 Aug 2020 20:28:16
	System	16 Aug 2020 20:28:16

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52916cc7-e0e9-452e-8db8-90a9ac0c2cd7'	System	16 Aug 2020 20:28:16
User entered 'No (N)'	System	16 Aug 2020 20:28:16

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52916cc7-e0e9-452e-8db8-90a9ac0c2cd7' User entered '16 Aug 2020 14:28'	System	16 Aug 2020 20:28:16
	System	16 Aug 2020 20:28:16

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b5d78e6b-2231-4ba1-bc07-bf9ae66df8df' User entered 'None (1)'	System	10 Aug 2020 16:43:37
	System	10 Aug 2020 16:43:37

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:12', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b5d78e6b-2231-4ba1-bc07-bf9ae66df8df' User entered 'No (N)'	System	10 Aug 2020 16:43:37
	System	10 Aug 2020 16:43:37



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:16', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b5d78e6b-2231-4ba1-bc07-bf9ae66df8df' User entered 'No (N)'	System	10 Aug 2020 16:43:37
	System	10 Aug 2020 16:43:37

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:23', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b5d78e6b-2231-4ba1-bc07-bf9ae66df8df' User entered 'None (1)'	System	10 Aug 2020 16:43:37
	System	10 Aug 2020 16:43:37

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b5d78e6b-2231-4ba1-bc07-bf9ae66df8df' User entered '10 Aug 2020 10:43'	System	10 Aug 2020 16:43:37
	System	10 Aug 2020 16:43:37

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 10:26'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 12:56'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0938f464-71ef-4da5-9d7c-ee0704f72349'	System	10 Aug 2020 21:48:52
User entered 'None (1)'	System	10 Aug 2020 21:48:52

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0938f464-71ef-4da5-9d7c-ee0704f72349'	System	10 Aug 2020 21:48:52
User entered 'No (N)'	System	10 Aug 2020 21:48:52



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:36', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0938f464-71ef-4da5-9d7c-ee0704f72349'	System	10 Aug 2020 21:48:52
User entered 'No (N)'	System	10 Aug 2020 21:48:52

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:42', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0938f464-71ef-4da5-9d7c-ee0704f72349'	System	10 Aug 2020 21:48:52
User entered 'None (1)'	System	10 Aug 2020 21:48:52

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0938f464-71ef-4da5-9d7c-ee0704f72349'	System	10 Aug 2020 21:48:52
User entered '10 Aug 2020 15:48'	System	10 Aug 2020 21:48:52

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 13:51'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 2'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:07', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '34938163-68d3-4a53-8586-ad3899c8bd4d'	System	11 Aug 2020 22:00:26
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 22:00:26

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '34938163-68d3-4a53-8586-ad3899c8bd4d' User entered 'No (N)'	System	11 Aug 2020 22:00:26
	System	11 Aug 2020 22:00:26



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:15', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '34938163-68d3-4a53-8586-ad3899c8bd4d' User entered 'No (N)'	System	11 Aug 2020 22:00:26
	System	11 Aug 2020 22:00:26

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:20', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '34938163-68d3-4a53-8586-ad3899c8bd4d' User entered 'None (1)'	System	11 Aug 2020 22:00:26
	System	11 Aug 2020 22:00:26

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '34938163-68d3-4a53-8586-ad3899c8bd4d'	System	11 Aug 2020 22:00:26
User entered '11 Aug 2020 16:00'	System	11 Aug 2020 22:00:26

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 3'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:03', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '05883c12-aff9-448c-9580-c03166ca389a' User entered 'None (1)'	System	12 Aug 2020 20:46:21
	System	12 Aug 2020 20:46:21

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:07', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '05883c12-aff9-448c-9580-c03166ca389a' User entered 'No (N)'	System	12 Aug 2020 20:46:21
	System	12 Aug 2020 20:46:21



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:12', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '05883c12-aff9-448c-9580-c03166ca389a' User entered 'No (N)'	System	12 Aug 2020 20:46:21
	System	12 Aug 2020 20:46:21

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:16', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '05883c12-aff9-448c-9580-c03166ca389a' User entered 'None (1)'	System	12 Aug 2020 20:46:21
	System	12 Aug 2020 20:46:21

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:19', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '05883c12-aff9-448c-9580-c03166ca389a' User entered '12 Aug 2020 14:46'	System	12 Aug 2020 20:46:21
	System	12 Aug 2020 20:46:21

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 4'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '02adb8db-c527-4096-a2d1-1f6cecf61623' User entered 'None (1)'	System	13 Aug 2020 18:25:47
	System	13 Aug 2020 18:25:47

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '02adb8db-c527-4096-a2d1-1f6cecf61623' User entered 'No (N)'	System	13 Aug 2020 18:25:47
	System	13 Aug 2020 18:25:47



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:36', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '02adb8db-c527-4096-a2d1-1f6cecf61623' User entered 'No (N)'	System	13 Aug 2020 18:25:47
	System	13 Aug 2020 18:25:47

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:40', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '02adb8db-c527-4096-a2d1-1f6cecf61623' User entered 'None (1)'	System	13 Aug 2020 18:25:47
	System	13 Aug 2020 18:25:47

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '02adb8db-c527-4096-a2d1-1f6cecf61623' User entered '13 Aug 2020 12:25'	System	13 Aug 2020 18:25:47
	System	13 Aug 2020 18:25:47

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 5'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:06', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '213251db-99d9-4d44-85ed-0603609e2ce4'	System	14 Aug 2020 19:14:25
User entered 'None (1)'	System	14 Aug 2020 19:14:25

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:10', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '213251db-99d9-4d44-85ed-0603609e2ce4'	System	14 Aug 2020 19:14:25
User entered 'No (N)'	System	14 Aug 2020 19:14:25



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '213251db-99d9-4d44-85ed-0603609e2ce4'	System	14 Aug 2020 19:14:25
User entered 'No (N)'	System	14 Aug 2020 19:14:25

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:19', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '213251db-99d9-4d44-85ed-0603609e2ce4' User entered 'None (1)'	System	14 Aug 2020 19:14:25
	System	14 Aug 2020 19:14:25

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:23', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '213251db-99d9-4d44-85ed-0603609e2ce4'	System	14 Aug 2020 19:14:25
User entered '14 Aug 2020 13:14'	System	14 Aug 2020 19:14:25

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 6'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:42', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e9c53e9f-182a-4741-be78-1fcc59cea577'	System	15 Aug 2020 22:05:57
User entered 'None (1)'	System	15 Aug 2020 22:05:57

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e9c53e9f-182a-4741-be78-1fcc59cea577'	System	15 Aug 2020 22:05:57
User entered 'No (N)'	System	15 Aug 2020 22:05:57



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:49', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e9c53e9f-182a-4741-be78-1fcc59cea577'	System	15 Aug 2020 22:05:57
User entered 'No (N)'	System	15 Aug 2020 22:05:57

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:53', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e9c53e9f-182a-4741-be78-1fcc59cea577'	System	15 Aug 2020 22:05:57
User entered 'None (1)'	System	15 Aug 2020 22:05:57

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:05:55', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e9c53e9f-182a-4741-be78-1fcc59cea577'	System	15 Aug 2020 22:05:57
User entered '15 Aug 2020 16:05'	System	15 Aug 2020 22:05:57

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 7'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:19', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e1ee0e6d-cf9f-4957-a285-ddb171c606fa' User entered 'None (1)'	System	16 Aug 2020 20:28:35
	System	16 Aug 2020 20:28:35

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e1ee0e6d-cf9f-4957-a285-ddb171c606fa' User entered 'No (N)'	System	16 Aug 2020 20:28:35
	System	16 Aug 2020 20:28:35



US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:25', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e1ee0e6d-cf9f-4957-a285-ddb171c606fa' User entered 'No (N)'	System	16 Aug 2020 20:28:35
	System	16 Aug 2020 20:28:35

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e1ee0e6d-cf9f-4957-a285-ddb171c606fa' User entered 'None (1)'	System	16 Aug 2020 20:28:35
	System	16 Aug 2020 20:28:35

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e1ee0e6d-cf9f-4957-a285-ddb171c606fa' User entered '16 Aug 2020 14:28'	System	16 Aug 2020 20:28:35
	System	16 Aug 2020 20:28:35

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:41', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a'	System	10 Aug 2020 16:44:14
User entered 'None (0)'	System	10 Aug 2020 16:44:14

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:44', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a' User entered 'None (0)'	System	10 Aug 2020 16:44:14
	System	10 Aug 2020 16:44:14



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a' User entered 'None (0)'	System	10 Aug 2020 16:44:14
	System	10 Aug 2020 16:44:14

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:51', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a' User entered 'None (0)'	System	10 Aug 2020 16:44:14
	System	10 Aug 2020 16:44:14

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:54', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a' User entered 'None (0)'	System	10 Aug 2020 16:44:14
	System	10 Aug 2020 16:44:14

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:43:57', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a'	System	10 Aug 2020 16:44:14
User entered 'None (0)'	System	10 Aug 2020 16:44:14

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:44:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a'	System	10 Aug 2020 16:44:14
User entered 'No (N)'	System	10 Aug 2020 16:44:14

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T10:44:09', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd4078995-7282-4413-a620-0362cdbd032a' User entered '10 Aug 2020 10:44'	System	10 Aug 2020 16:44:14
	System	10 Aug 2020 16:44:14

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 10:26'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 12:56'	System	10 Aug 2020 16:37:01



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:56', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered 'None (0)'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:48:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered 'None (0)'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:49:03', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered 'None (0)'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:49:06', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered 'None (0)'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:49:09', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered 'None (0)'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:49:12', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered 'None (0)'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:49:25', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered 'No (N)'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-10T15:49:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '0b475d70-efc7-4fce-ab6d-12f1ceef0a07' User entered '10 Aug 2020 15:49'	System	10 Aug 2020 21:49:33
	System	10 Aug 2020 21:49:33

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '10 Aug 2020 13:51'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 2'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:30', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5' User entered 'None (0)'	System	11 Aug 2020 22:01:00
	System	11 Aug 2020 22:01:00

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:36', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5' User entered 'None (0)'	System	11 Aug 2020 22:01:00
	System	11 Aug 2020 22:01:00

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:39', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5' User entered 'None (0)'	System	11 Aug 2020 22:01:00
	System	11 Aug 2020 22:01:00

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5' User entered 'None (0)'	System	11 Aug 2020 22:01:00
	System	11 Aug 2020 22:01:00



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:46', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5' User entered 'None (0)'	System	11 Aug 2020 22:01:00
	System	11 Aug 2020 22:01:00

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:50', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5' User entered 'None (0)'	System	11 Aug 2020 22:01:00
	System	11 Aug 2020 22:01:00

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:55', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5'	System	11 Aug 2020 22:01:00
User entered 'No (N)'	System	11 Aug 2020 22:01:00

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-11T16:00:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '312c61b0-93b7-4202-84be-0367a94042d5'	System	11 Aug 2020 22:01:00
User entered '11 Aug 2020 16:00'	System	11 Aug 2020 22:01:00

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 3'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:25', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered 'None (0)'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered 'None (0)'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered 'None (0)'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:36', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered 'None (0)'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:40', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered 'None (0)'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered 'None (0)'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered 'No (N)'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-12T14:46:50', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4015d56a-7ce1-4f70-9876-8e58c7f63ebd' User entered '12 Aug 2020 14:46'	System	12 Aug 2020 20:46:52
	System	12 Aug 2020 20:46:52

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 16:37:01



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 4'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:49', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered 'None (0)'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:52', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered 'None (0)'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:55', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered 'None (0)'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:25:58', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered 'None (0)'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:26:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered 'None (0)'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:26:04', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered 'None (0)'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:26:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered 'No (N)'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-13T12:26:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a8bf5643-40b9-44e8-81f0-8bc8726be04f' User entered '13 Aug 2020 12:26'	System	13 Aug 2020 18:26:13
	System	13 Aug 2020 18:26:13

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 5'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67' User entered 'None (0)'	System	14 Aug 2020 19:15:04
	System	14 Aug 2020 19:15:04

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:36', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67' User entered 'None (0)'	System	14 Aug 2020 19:15:04
	System	14 Aug 2020 19:15:04

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:40', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67' User entered 'None (0)'	System	14 Aug 2020 19:15:04
	System	14 Aug 2020 19:15:04



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67' User entered 'None (0)'	System	14 Aug 2020 19:15:04
	System	14 Aug 2020 19:15:04

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:46', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67' User entered 'None (0)'	System	14 Aug 2020 19:15:04
	System	14 Aug 2020 19:15:04

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:49', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67' User entered 'None (0)'	System	14 Aug 2020 19:15:04
	System	14 Aug 2020 19:15:04

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:14:56', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67' User entered 'No (N)'	System	14 Aug 2020 19:15:04
	System	14 Aug 2020 19:15:04

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-14T13:15:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '13231539-4e03-4f41-b842-136bc44d5e67'	System	14 Aug 2020 19:15:04
User entered '14 Aug 2020 13:15'	System	14 Aug 2020 19:15:04

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 6'	System	10 Aug 2020 16:37:01



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3' User entered 'None (0)'	System	15 Aug 2020 22:06:31
	System	15 Aug 2020 22:06:31

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:04', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3' User entered 'None (0)'	System	15 Aug 2020 22:06:31
	System	15 Aug 2020 22:06:31

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:07', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3' User entered 'None (0)'	System	15 Aug 2020 22:06:31
	System	15 Aug 2020 22:06:31

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3' User entered 'None (0)'	System	15 Aug 2020 22:06:31
	System	15 Aug 2020 22:06:31

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3' User entered 'None (0)'	System	15 Aug 2020 22:06:31
	System	15 Aug 2020 22:06:31

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:17', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3' User entered 'None (0)'	System	15 Aug 2020 22:06:31
	System	15 Aug 2020 22:06:31

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3' User entered 'No (N)'	System	15 Aug 2020 22:06:31
	System	15 Aug 2020 22:06:31

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-15T16:06:27', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a71f7142-2cc8-42f9-8996-e4a68f1c8af3'	System	15 Aug 2020 22:06:31
User entered '15 Aug 2020 16:06'	System	15 Aug 2020 22:06:31



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 7'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:37', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered 'None (0)'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:41', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered 'None (0)'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered 'None (0)'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:46', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered 'None (0)'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered 'None (0)'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03



US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:51', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered 'None (0)'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:28:57', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered 'No (N)'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-08-16T14:29:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b87c155e-69a3-412e-b571-d4ee00d075e0' User entered '16 Aug 2020 14:29'	System	16 Aug 2020 20:29:03
	System	16 Aug 2020 20:29:03

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 16:37:01

US3332033

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 01:44:24

US3332033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	22 Aug 2020 01:44:31
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Aug 2020 01:44:31
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 01:44:31
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Aug 2020 01:44:24
User entered '21 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 01:44:24

US3332033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 01:44:24



US3332033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 01:44:24

US3332033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 01:44:37

US3332033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	22 Aug 2020 01:44:37

US3332033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:13:27

US3332033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '27 Aug 2020'	Ty Henry (b) (4)	08 Sep 2020 15:13:27

US3332033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	08 Sep 2020 15:13:27

US3332033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:13:27

US3332033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:13:41



US3332033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	08 Sep 2020 15:13:41

US3332033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:14:05

US3332033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '31 Aug 2020'	Ty Henry (b) (4)	08 Sep 2020 15:14:05

US3332033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	08 Sep 2020 15:14:05

US3332033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:14:05

US3332033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:14:10

US3332033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	08 Sep 2020 15:14:10

US3332033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:22:51



US3332033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '11 Sep 2020'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:22:51

US3332033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Clinic (Clinic)'	Colby Bostock (b) (4)	11 Sep 2020 15:22:51

US3332033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'VISIT2'	System	11 Sep 2020 15:22:51

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User accepted default value 'Pre-Dose (PREDOSE)'	Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '11 Sep 2020'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '08:06'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '11 Sep 2020 08:06'	System	11 Sep 2020 15:23:50



US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '97.1' F	Colby Bostock (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Oral (Oral)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 15:24:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Sep 2020 15:24:19
User entered '59' reason for change: Data Entry Error	Colby Bostock (b) (4)	11 Sep 2020 15:24:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 15:23:50
User entered empty.	System	11 Sep 2020 15:23:50
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'bpm'	System	11 Sep 2020 15:24:19
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 15:24:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Sep 2020 15:24:19
User entered '22' reason for change: Data Entry Error	Colby Bostock (b) (4)	11 Sep 2020 15:24:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 15:23:50
User entered empty.	System	11 Sep 2020 15:23:50
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'breaths/min'	System	11 Sep 2020 15:24:19
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) System	16 Sep 2020 23:49:49
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:49:49
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:49:49
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	11 Sep 2020 15:24:19
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 15:24:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 15:24:19
User entered '162' reason for change: Data Entry Error	Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:24:19
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 15:23:50
User entered empty.	Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:23:50



US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	11 Sep 2020 15:24:19
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 15:24:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Sep 2020 15:24:19
User entered '88' reason for change: Data Entry Error	Colby Bostock (b) (4)	11 Sep 2020 15:24:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 15:23:50
User entered empty.	System	11 Sep 2020 15:23:50
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	11 Sep 2020 15:24:19
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User accepted default value 'Post-Dose (POSTDOSE)'	Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 15:49:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Sep 2020 15:23:50
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '09:44' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '11 Sep 2020 09:44'	System	11 Sep 2020 15:49:26
User entered empty.	System	11 Sep 2020 15:23:50



US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '60' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'bpm'	System	11 Sep 2020 15:49:26
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '20' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'breaths/min'	System	11 Sep 2020 15:49:26
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '148' reason for change: Data Entry Error	(b) (4)	
	Megan Grimmatt (b) (4)	11 Sep 2020 15:49:26
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Sep 2020 15:23:50
	(b) (4)	



US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	11 Sep 2020 15:49:26
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '80' reason for change: Data Entry Error	Megan Grimm (b) (4)	11 Sep 2020 15:49:26
User entered empty.	Colby Bostock (b) (4)	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	11 Sep 2020 15:49:26
User entered empty.	System	11 Sep 2020 15:23:50

US3332033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:24:54

US3332033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '11 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:24:54

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	Colby Bostock (b) (4)	11 Sep 2020 15:25:48



US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '11 Sep 2020'	Colby Bostock (b) (4)	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '09:08'	Colby Bostock (b) (4)	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '11 Sep 2020 09:08'	System	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Left Arm (LEFT ARM)'	Colby Bostock (b) (4)	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'ONCE'	System	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 15:25:48

US3332033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:26:02



US3332033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '11 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:02

US3332033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '08:31'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:02

US3332033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '11 Sep 2020 08:31'	System	11 Sep 2020 15:26:02

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '11 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '08:28'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '11 Sep 2020 08:28'	System	11 Sep 2020 15:26:19



US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'No (N)'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered empty.	System	11 Sep 2020 15:26:19

US3332033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	11 Sep 2020 15:26:23

US3332033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'I'	System	11 Sep 2020 15:26:23

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:00', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b414a348-180e-4b31-917c-6ca68da42b8c' User entered 'Yes (Y)'	System	11 Sep 2020 15:41:41
	System	11 Sep 2020 15:41:41



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:06', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b414a348-180e-4b31-917c-6ca68da42b8c' User entered '98.0'	System	11 Sep 2020 15:41:41
	System	11 Sep 2020 15:41:41

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b414a348-180e-4b31-917c-6ca68da42b8c' User entered 'No (N)'	System	11 Sep 2020 15:41:41
	System	11 Sep 2020 15:41:41

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:18', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b414a348-180e-4b31-917c-6ca68da42b8c' User entered '11 Sep 2020 09:41'	System	11 Sep 2020 15:41:41
	System	11 Sep 2020 15:41:41

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 09:28'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 11:58'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:13', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'f179b43f-e450-4a8d-b3bc-4352d78c4b6b' User entered 'Yes (Y)'	System	11 Sep 2020 19:33:35
	System	11 Sep 2020 19:33:35

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:21', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'f179b43f-e450-4a8d-b3bc-4352d78c4b6b' User entered '98.1'	System	11 Sep 2020 19:33:35
	System	11 Sep 2020 19:33:35



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:26', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'f179b43f-e450-4a8d-b3bc-4352d78c4b6b'	System	11 Sep 2020 19:33:35
User entered 'No (N)'	System	11 Sep 2020 19:33:35

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:31', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'f179b43f-e450-4a8d-b3bc-4352d78c4b6b' User entered '11 Sep 2020 13:33'	System	11 Sep 2020 19:33:35
	System	11 Sep 2020 19:33:35

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 12:53'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 2'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:41:54', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fc25280c-94c1-48f4-84f2-f4c5422da3a9' User entered 'Yes (Y)'	System	12 Sep 2020 21:42:26
	System	12 Sep 2020 21:42:26

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:09', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fc25280c-94c1-48f4-84f2-f4c5422da3a9' User entered '100.5'	System	12 Sep 2020 21:42:26
	System	12 Sep 2020 21:42:26

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:13', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fc25280c-94c1-48f4-84f2-f4c5422da3a9'	System	12 Sep 2020 21:42:26
User entered 'No (N)'	System	12 Sep 2020 21:42:26



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:21', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fc25280c-94c1-48f4-84f2-f4c5422da3a9'	System	12 Sep 2020 21:42:26
User entered '12 Sep 2020 15:42'	System	12 Sep 2020 21:42:26

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 3'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:23:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e828346a-a912-4ba2-a984-c8d9e0892884' User entered 'Yes (Y)'	System	14 Sep 2020 05:24:43
	System	14 Sep 2020 05:24:43

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:24:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e828346a-a912-4ba2-a984-c8d9e0892884' User entered '97.9'	System	14 Sep 2020 05:24:43
	System	14 Sep 2020 05:24:43

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:24:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e828346a-a912-4ba2-a984-c8d9e0892884' User entered 'No (N)'	System	14 Sep 2020 05:24:43
	System	14 Sep 2020 05:24:43

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:24:39', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e828346a-a912-4ba2-a984-c8d9e0892884' User entered '13 Sep 2020 23:24'	System	14 Sep 2020 05:24:43
	System	14 Sep 2020 05:24:43



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 4'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '75c7e6da-2e7a-4f24-b0f3-39cf00f8c270' User entered 'Yes (Y)'	System	15 Sep 2020 02:56:37
	System	15 Sep 2020 02:56:37

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '75c7e6da-2e7a-4f24-b0f3-39cf00f8c270' User entered '98.0'	System	15 Sep 2020 02:56:37
	System	15 Sep 2020 02:56:37

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '75c7e6da-2e7a-4f24-b0f3-39cf00f8c270'	System	15 Sep 2020 02:56:37
User entered 'No (N)'	System	15 Sep 2020 02:56:37

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:34', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '75c7e6da-2e7a-4f24-b0f3-39cf00f8c270' User entered '14 Sep 2020 20:56'	System	15 Sep 2020 02:56:37
	System	15 Sep 2020 02:56:37

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:25:48



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 5'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:06', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd926e53b-3eb3-4ba3-8cf6-b8022d49fc3e' User entered 'Yes (Y)'	System	15 Sep 2020 22:16:27
	System	15 Sep 2020 22:16:27

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:12', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd926e53b-3eb3-4ba3-8cf6-b8022d49fc3e' User entered '97.7'	System	15 Sep 2020 22:16:27
	System	15 Sep 2020 22:16:27

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:17', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd926e53b-3eb3-4ba3-8cf6-b8022d49fc3e' User entered 'No (N)'	System	15 Sep 2020 22:16:27
	System	15 Sep 2020 22:16:27

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd926e53b-3eb3-4ba3-8cf6-b8022d49fc3e' User entered '15 Sep 2020 16:16'	System	15 Sep 2020 22:16:27
	System	15 Sep 2020 22:16:27

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:25:48



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 6'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '97d712a6-ca3b-4c2f-a13d-ddeec164e4a7' User entered 'Yes (Y)'	System	17 Sep 2020 02:51:40
	System	17 Sep 2020 02:51:40

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '97d712a6-ca3b-4c2f-a13d-ddeec164e4a7' User entered '98.3'	System	17 Sep 2020 02:51:40
	System	17 Sep 2020 02:51:40

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '97d712a6-ca3b-4c2f-a13d-ddeec164e4a7'	System	17 Sep 2020 02:51:40
User entered 'No (N)'	System	17 Sep 2020 02:51:40

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:36', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '97d712a6-ca3b-4c2f-a13d-ddeec164e4a7' User entered '16 Sep 2020 20:51'	System	17 Sep 2020 02:51:40
	System	17 Sep 2020 02:51:40

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 7'	System	11 Sep 2020 15:25:48



US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:01:58', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd65105ce-8db8-428d-832f-9fda396f0730' User entered 'Yes (Y)'	System	18 Sep 2020 03:02:15
	System	18 Sep 2020 03:02:15

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:05', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd65105ce-8db8-428d-832f-9fda396f0730' User entered '98.2'	System	18 Sep 2020 03:02:15
	System	18 Sep 2020 03:02:15

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:09', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd65105ce-8db8-428d-832f-9fda396f0730'	System	18 Sep 2020 03:02:15
User entered 'No (N)'	System	18 Sep 2020 03:02:15

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:12', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd65105ce-8db8-428d-832f-9fda396f0730' User entered '17 Sep 2020 21:02'	System	18 Sep 2020 03:02:15
	System	18 Sep 2020 03:02:15

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd7363522-c5a8-48ed-a7d9-25516570a60a' User entered 'None (1)'	System	11 Sep 2020 15:41:47
	System	11 Sep 2020 15:41:47



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd7363522-c5a8-48ed-a7d9-25516570a60a' User entered 'No (N)'	System	11 Sep 2020 15:41:47
	System	11 Sep 2020 15:41:47

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:37', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd7363522-c5a8-48ed-a7d9-25516570a60a' User entered 'No (N)'	System	11 Sep 2020 15:41:47
	System	11 Sep 2020 15:41:47

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:41', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd7363522-c5a8-48ed-a7d9-25516570a60a' User entered 'None (1)'	System	11 Sep 2020 15:41:47
	System	11 Sep 2020 15:41:47

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'd7363522-c5a8-48ed-a7d9-25516570a60a' User entered '11 Sep 2020 09:41'	System	11 Sep 2020 15:41:47
	System	11 Sep 2020 15:41:47

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 09:28'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 11:58'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:38', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4b43a9ba-875a-4180-94f2-d7247dcdf590'	System	11 Sep 2020 19:33:57
User entered 'None (1)'	System	11 Sep 2020 19:33:57



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4b43a9ba-875a-4180-94f2-d7247dcdf590' User entered 'No (N)'	System	11 Sep 2020 19:33:57
	System	11 Sep 2020 19:33:57

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4b43a9ba-875a-4180-94f2-d7247dcdf590' User entered 'No (N)'	System	11 Sep 2020 19:33:57
	System	11 Sep 2020 19:33:57

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:51', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4b43a9ba-875a-4180-94f2-d7247dcdf590'	System	11 Sep 2020 19:33:57
User entered 'None (1)'	System	11 Sep 2020 19:33:57

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:33:55', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4b43a9ba-875a-4180-94f2-d7247dcdf590' User entered '11 Sep 2020 13:33'	System	11 Sep 2020 19:33:57
	System	11 Sep 2020 19:33:57

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 12:53'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 2'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '925017d0-77ba-473e-a31d-37eb5e32595f'	System	12 Sep 2020 21:42:56
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 21:42:56



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:36', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '925017d0-77ba-473e-a31d-37eb5e32595f' User entered 'No (N)'	System	12 Sep 2020 21:42:56
	System	12 Sep 2020 21:42:56

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '925017d0-77ba-473e-a31d-37eb5e32595f' User entered 'No (N)'	System	12 Sep 2020 21:42:56
	System	12 Sep 2020 21:42:56

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:50', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '925017d0-77ba-473e-a31d-37eb5e32595f' User entered 'None (1)'	System	12 Sep 2020 21:42:56
	System	12 Sep 2020 21:42:56

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:53', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '925017d0-77ba-473e-a31d-37eb5e32595f' User entered '12 Sep 2020 15:42'	System	12 Sep 2020 21:42:56
	System	12 Sep 2020 21:42:56

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 3'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:24:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ea5f452-ae1-4395-a6d0-64cb8a5f90fd' User entered 'None (1)'	System	14 Sep 2020 05:25:05
	System	14 Sep 2020 05:25:05



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:24:51', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ea5f452-eae1-4395-a6d0-64cb8a5f90fd' User entered 'No (N)'	System	14 Sep 2020 05:25:05
	System	14 Sep 2020 05:25:05

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:24:54', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ea5f452-eae1-4395-a6d0-64cb8a5f90fd' User entered 'No (N)'	System	14 Sep 2020 05:25:05
	System	14 Sep 2020 05:25:05

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:24:58', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ea5f452-ae1-4395-a6d0-64cb8a5f90fd' User entered 'None (1)'	System	14 Sep 2020 05:25:05
	System	14 Sep 2020 05:25:05

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:02', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ea5f452-ae1-4395-a6d0-64cb8a5f90fd' User entered '13 Sep 2020 23:25'	System	14 Sep 2020 05:25:05
	System	14 Sep 2020 05:25:05

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 4'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4313d925-c19f-4f58-9fe2-aec92b67bed4' User entered 'None (1)'	System	15 Sep 2020 02:57:01
	System	15 Sep 2020 02:57:01



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4313d925-c19f-4f58-9fe2-aec92b67bed4' User entered 'No (N)'	System	15 Sep 2020 02:57:01
	System	15 Sep 2020 02:57:01

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:51', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4313d925-c19f-4f58-9fe2-aec92b67bed4' User entered 'No (N)'	System	15 Sep 2020 02:57:01
	System	15 Sep 2020 02:57:01

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:54', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4313d925-c19f-4f58-9fe2-aec92b67bed4' User entered 'None (1)'	System	15 Sep 2020 02:57:01
	System	15 Sep 2020 02:57:01

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:56:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4313d925-c19f-4f58-9fe2-aec92b67bed4'	System	15 Sep 2020 02:57:01
User entered '14 Sep 2020 20:56'	System	15 Sep 2020 02:57:01

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 5'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:31', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b6d5dc9d-3486-4695-8056-c8726c432d43'	System	15 Sep 2020 22:16:50
User entered 'None (1)'	System	15 Sep 2020 22:16:50



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b6d5dc9d-3486-4695-8056-c8726c432d43'	System	15 Sep 2020 22:16:50
User entered 'No (N)'	System	15 Sep 2020 22:16:50

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:39', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b6d5dc9d-3486-4695-8056-c8726c432d43'	System	15 Sep 2020 22:16:50
User entered 'No (N)'	System	15 Sep 2020 22:16:50

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:42', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b6d5dc9d-3486-4695-8056-c8726c432d43'	System	15 Sep 2020 22:16:50
User entered 'None (1)'	System	15 Sep 2020 22:16:50

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b6d5dc9d-3486-4695-8056-c8726c432d43'	System	15 Sep 2020 22:16:50
User entered '15 Sep 2020 16:16'	System	15 Sep 2020 22:16:50

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 6'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:42', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3e993529-9a6a-49ba-b988-dc2fb35b211f' User entered 'None (1)'	System	17 Sep 2020 02:51:59
	System	17 Sep 2020 02:51:59



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3e993529-9a6a-49ba-b988-dc2fb35b211f' User entered 'No (N)'	System	17 Sep 2020 02:51:59
	System	17 Sep 2020 02:51:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3e993529-9a6a-49ba-b988-dc2fb35b211f' User entered 'No (N)'	System	17 Sep 2020 02:51:59
	System	17 Sep 2020 02:51:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:51', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3e993529-9a6a-49ba-b988-dc2fb35b211f' User entered 'None (1)'	System	17 Sep 2020 02:51:59
	System	17 Sep 2020 02:51:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:51:55', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3e993529-9a6a-49ba-b988-dc2fb35b211f' User entered '16 Sep 2020 20:51'	System	17 Sep 2020 02:51:59
	System	17 Sep 2020 02:51:59

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 7'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:18', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '59492bf5-ad22-4049-960c-8ede04cfe68a' User entered 'None (1)'	System	18 Sep 2020 03:02:37
	System	18 Sep 2020 03:02:37



US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '59492bf5-ad22-4049-960c-8ede04cfe68a' User entered 'No (N)'	System	18 Sep 2020 03:02:37
	System	18 Sep 2020 03:02:37

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:25', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '59492bf5-ad22-4049-960c-8ede04cfe68a' User entered 'No (N)'	System	18 Sep 2020 03:02:37
	System	18 Sep 2020 03:02:37

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '59492bf5-ad22-4049-960c-8ede04cfe68a' User entered 'None (1)'	System	18 Sep 2020 03:02:37
	System	18 Sep 2020 03:02:37

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '59492bf5-ad22-4049-960c-8ede04cfe68a' User entered '17 Sep 2020 21:02'	System	18 Sep 2020 03:02:37
	System	18 Sep 2020 03:02:37

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:52', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered 'None (0)'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:41:55', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered 'None (0)'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:42:00', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered 'None (0)'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:42:03', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered 'None (0)'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:42:07', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered 'None (0)'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:42:10', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered 'None (0)'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:42:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered 'No (N)'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T09:42:18', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '52faf276-c344-4ae2-8e89-0e4134cb7874' User entered '11 Sep 2020 09:42'	System	11 Sep 2020 15:42:21
	System	11 Sep 2020 15:42:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 09:28'	System	11 Sep 2020 15:25:48



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 11:58'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522'	System	11 Sep 2020 19:34:26
User entered 'None (0)'	System	11 Sep 2020 19:34:26

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:04', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522' User entered 'None (0)'	System	11 Sep 2020 19:34:26
	System	11 Sep 2020 19:34:26

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:07', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522' User entered 'None (0)'	System	11 Sep 2020 19:34:26
	System	11 Sep 2020 19:34:26

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522' User entered 'None (0)'	System	11 Sep 2020 19:34:26
	System	11 Sep 2020 19:34:26

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522' User entered 'None (0)'	System	11 Sep 2020 19:34:26
	System	11 Sep 2020 19:34:26

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:16', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522' User entered 'None (0)'	System	11 Sep 2020 19:34:26
	System	11 Sep 2020 19:34:26



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:20', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522'	System	11 Sep 2020 19:34:26
User entered 'No (N)'	System	11 Sep 2020 19:34:26

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-11T13:34:23', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a0cb3f72-a9eb-4a0c-b87a-84c8f4a5c522'	System	11 Sep 2020 19:34:26
User entered '11 Sep 2020 13:34'	System	11 Sep 2020 19:34:26

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '11 Sep 2020 12:53'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 2'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:42:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered 'None (0)'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:43:02', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered 'None (0)'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:43:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered 'None (0)'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:43:12', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered 'None (0)'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:43:16', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered 'None (0)'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:43:20', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered 'None (0)'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:43:26', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered 'No (N)'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-12T15:43:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b60df778-d8b0-4382-882c-038dbf014866' User entered '12 Sep 2020 15:43'	System	12 Sep 2020 21:43:31
	System	12 Sep 2020 21:43:31

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 3'	System	11 Sep 2020 15:25:48



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered 'None (0)'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered 'None (0)'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered 'None (0)'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:18', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered 'None (0)'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:21', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered 'None (0)'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered 'None (0)'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered 'No (N)'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-13T23:25:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '5a5bdb8d-4702-4f6e-a291-35770938480d' User entered '13 Sep 2020 23:25'	System	14 Sep 2020 05:25:37
	System	14 Sep 2020 05:25:37



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 4'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:05', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered 'None (0)'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered 'None (0)'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered 'None (0)'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:13', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered 'None (0)'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:16', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered 'None (0)'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:18', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered 'None (0)'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered 'No (N)'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-14T20:57:26', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '068e9d86-0eec-481e-aa68-afed69e34144' User entered '14 Sep 2020 20:57'	System	15 Sep 2020 02:57:29
	System	15 Sep 2020 02:57:29

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 5'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:53', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32'	System	15 Sep 2020 22:17:30
User entered 'None (0)'	System	15 Sep 2020 22:17:30

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:16:57', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32'	System	15 Sep 2020 22:17:30
User entered 'None (0)'	System	15 Sep 2020 22:17:30



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:17:00', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32'	System	15 Sep 2020 22:17:30
User entered 'None (0)'	System	15 Sep 2020 22:17:30

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:17:07', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32' User entered 'None (0)'	System	15 Sep 2020 22:17:30
	System	15 Sep 2020 22:17:30

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:17:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32'	System	15 Sep 2020 22:17:30
User entered 'None (0)'	System	15 Sep 2020 22:17:30

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:17:17', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32'	System	15 Sep 2020 22:17:30
User entered 'None (0)'	System	15 Sep 2020 22:17:30

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:17:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32'	System	15 Sep 2020 22:17:30
User entered 'No (N)'	System	15 Sep 2020 22:17:30

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-15T16:17:25', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '76e4889d-13ca-41d0-996d-976025372c32'	System	15 Sep 2020 22:17:30
User entered '15 Sep 2020 16:17'	System	15 Sep 2020 22:17:30

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:25:48



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 6'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:00', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029' User entered 'None (0)'	System	17 Sep 2020 02:52:21
	System	17 Sep 2020 02:52:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:03', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029' User entered 'None (0)'	System	17 Sep 2020 02:52:21
	System	17 Sep 2020 02:52:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:06', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029' User entered 'None (0)'	System	17 Sep 2020 02:52:21
	System	17 Sep 2020 02:52:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029' User entered 'None (0)'	System	17 Sep 2020 02:52:21
	System	17 Sep 2020 02:52:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:11', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029' User entered 'None (0)'	System	17 Sep 2020 02:52:21
	System	17 Sep 2020 02:52:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:13', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029' User entered 'None (0)'	System	17 Sep 2020 02:52:21
	System	17 Sep 2020 02:52:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:16', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029' User entered 'No (N)'	System	17 Sep 2020 02:52:21
	System	17 Sep 2020 02:52:21



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-16T20:52:19', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'fac40f72-c239-4e47-869d-b3cfd1ae2029'	System	17 Sep 2020 02:52:21
User entered '16 Sep 2020 20:52'	System	17 Sep 2020 02:52:21

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	11 Sep 2020 15:25:48
User entered 'Day 7'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:40', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered 'None (0)'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered 'None (0)'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:46', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered 'None (0)'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:50', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered 'None (0)'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05



US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:53', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered 'None (0)'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:55', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered 'None (0)'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:02:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered 'No (N)'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-09-17T21:03:03', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'e6d605f8-7b5c-4a11-973c-9cb592dbdc4c' User entered '17 Sep 2020 21:03'	System	18 Sep 2020 03:03:05
	System	18 Sep 2020 03:03:05

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:25:48

US3332033

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:09:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:25:48

US3332033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Colby Bostock (b) (4)	18 Sep 2020 17:07:47

US3332033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '18 Sep 2020'	Colby Bostock (b) (4)	18 Sep 2020 17:07:47



US3332033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Contact Made (CONTACT MADE)'	Colby Bostock (b) (4)	18 Sep 2020 17:07:47

US3332033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	18 Sep 2020 17:07:47

US3332033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Colby Bostock (b) (4)	18 Sep 2020 17:07:51

US3332033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	18 Sep 2020 17:07:51

US3332033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Ty Henry (b) (4)	28 Sep 2020 17:19:58

US3332033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '26 Sep 2020'	Ty Henry (b) (4)	28 Sep 2020 17:19:58

US3332033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	28 Sep 2020 17:19:58

US3332033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	Ty Henry (b) (4)	28 Sep 2020 17:19:58



US3332033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Ty Henry (b) (4)	28 Sep 2020 17:20:05

US3332033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	28 Sep 2020 17:20:05

US3332033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	02 Oct 2020 19:07:06

US3332033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered '2 Oct 2020'	Colby Bostock (b) (4)	02 Oct 2020 19:07:06

US3332033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colby Bostock (b) (4) (b) (4)	02 Oct 2020 19:07:06

US3332033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	02 Oct 2020 19:07:06

US3332033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:04
User entered 'Yes (Y)'	Colby Bostock (b) (4)	02 Oct 2020 19:07:10

US3332033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	02 Oct 2020 19:07:10



US3332033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:26:54

US3332033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:26:54

US3332033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:26:54

**US3332033**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:09:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'VISIT3'	System	13 Oct 2020 00:26:54

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '08:06'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '12 Oct 2020 08:06'	System	13 Oct 2020 00:27:43



US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '59'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'bpm'	System	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'breaths/min'	System	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '140'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43



US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '78'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'mmHg'	System	13 Oct 2020 00:27:43

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34

US3332033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34

US3332033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:53

US3332033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:27:53

US3332033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:28:22



US3332033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:28:22

US3332033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered '08:31'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:28:22

US3332033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered '12 Oct 2020 08:31'	System	13 Oct 2020 00:28:22

US3332033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 00:28:39

US3332033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:34
User entered 'I'	System	13 Oct 2020 00:28:39

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 64'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-10-10T08:09:19', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b24310c3-b21f-491b-932a-5498474136e0' User entered 'No (N)'	System	10 Oct 2020 14:09:39
	System	10 Oct 2020 14:09:39

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-10-10T08:09:27', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b24310c3-b21f-491b-932a-5498474136e0'	System	10 Oct 2020 14:09:39
User entered 'No (N)'	System	10 Oct 2020 14:09:39



US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-10-10T08:09:37', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b24310c3-b21f-491b-932a-5498474136e0' User entered '10 Oct 2020 08:09:37'	System	10 Oct 2020 14:09:39
	System	10 Oct 2020 14:09:39

US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 16:37:01

US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 71'	System	10 Aug 2020 16:37:01

US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03



US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03



US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03



US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:05:03
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 78'	System	10 Aug 2020 16:37:01



US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-10-24T16:03:50', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '74483df1-789a-4257-bb04-a28a6b47f8ac' User entered 'No (N)'	System	24 Oct 2020 22:04:12
	System	24 Oct 2020 22:04:12

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-10-24T16:03:58', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '74483df1-789a-4257-bb04-a28a6b47f8ac'	System	24 Oct 2020 22:04:12
User entered 'No (N)'	System	24 Oct 2020 22:04:12

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-10-24T16:04:10', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '74483df1-789a-4257-bb04-a28a6b47f8ac' User entered '24 Oct 2020 16:04:10'	System	24 Oct 2020 22:04:12
	System	24 Oct 2020 22:04:12

US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 92'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-08T17:39:17', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '936f4020-90ab-419c-8c3d-7e2298d2b564'	System	09 Nov 2020 00:39:33
User entered 'No (N)'	System	09 Nov 2020 00:39:33

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-08T17:39:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '936f4020-90ab-419c-8c3d-7e2298d2b564'	System	09 Nov 2020 00:39:33
User entered 'No (N)'	System	09 Nov 2020 00:39:33



**US3332033**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-08T17:39:30', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '936f4020-90ab-419c-8c3d-7e2298d2b564' User entered '08 Nov 2020 17:39:30'	System	09 Nov 2020 00:39:33
	System	09 Nov 2020 00:39:33

US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 16:37:01

US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered 'Day 99'	System	10 Aug 2020 16:37:01

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-14T08:53:39', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3997ec98-e1cb-4c9f-b77e-d54cafb3b08'	System	14 Nov 2020 15:53:59
User entered 'No (N)'	System	14 Nov 2020 15:53:59

US3332033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-14T08:53:46', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3997ec98-e1cb-4c9f-b77e-d54cafb3b08'	System	14 Nov 2020 15:53:59
User entered 'No (N)'	System	14 Nov 2020 15:53:59

**US3332033**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-14T08:53:57', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3997ec98-e1cb-4c9f-b77e-d54cafb3b08'	System	14 Nov 2020 15:53:59
User entered '14 Nov 2020 08:53:57'	System	14 Nov 2020 15:53:59

US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 16:37:01



US3332033

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:49
Data entry locked.	System	10 Aug 2020 16:37:01
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 16:37:01

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-19T11:44:15', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '96e9069d-45de-4c84-b40c-40fbfef6201'	System	19 Nov 2020 18:44:33
User entered 'No (N)'	System	19 Nov 2020 18:44:33

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-19T11:44:23', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '96e9069d-45de-4c84-b40c-40fbfef6201'	System	19 Nov 2020 18:44:33
User entered 'No (N)'	System	19 Nov 2020 18:44:33

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-19T11:44:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '96e9069d-45de-4c84-b40c-40fbfef6201' User entered '19 Nov 2020 11:44:29'	System	19 Nov 2020 18:44:33
	System	19 Nov 2020 18:44:33

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-25T09:33:37', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'df7ee59f-1b0a-4813-bb52-01e9490407f8'	System	25 Nov 2020 16:33:51
User entered 'No (N)'	System	25 Nov 2020 16:33:51

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-25T09:33:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'df7ee59f-1b0a-4813-bb52-01e9490407f8'	System	25 Nov 2020 16:33:51
User entered 'No (N)'	System	25 Nov 2020 16:33:51

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-11-25T09:33:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'df7ee59f-1b0a-4813-bb52-01e9490407f8' User entered '25 Nov 2020 09:33:48'	System	25 Nov 2020 16:33:51
	System	25 Nov 2020 16:33:51

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-02T00:02:30', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '706a9040-9841-4ce6-b8b7-7ede182d7e5e' User entered 'No (N)'	System	02 Dec 2020 07:02:44
	System	02 Dec 2020 07:02:44

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-02T00:02:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '706a9040-9841-4ce6-b8b7-7ede182d7e5e' User entered 'No (N)'	System	02 Dec 2020 07:02:44
	System	02 Dec 2020 07:02:44



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-02T00:02:42', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '706a9040-9841-4ce6-b8b7-7ede182d7e5e' User entered '02 Dec 2020 00:02:42'	System	02 Dec 2020 07:02:44
	System	02 Dec 2020 07:02:44

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-09T10:35:31', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '14fe44a3-0efd-4d44-acfb-5706b6c0e806'	System	09 Dec 2020 17:35:49
User entered 'No (N)'	System	09 Dec 2020 17:35:49

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-09T10:35:39', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '14fe44a3-0efd-4d44-acfb-5706b6c0e806'	System	09 Dec 2020 17:35:49
User entered 'No (N)'	System	09 Dec 2020 17:35:49

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-09T10:35:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '14fe44a3-0efd-4d44-acfb-5706b6c0e806' User entered '09 Dec 2020 10:35:43'	System	09 Dec 2020 17:35:49
	System	09 Dec 2020 17:35:49

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-16T10:25:01', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4d3be6d2-da0c-4080-b695-2077222cb945'	System	16 Dec 2020 17:25:49
User entered 'Yes (Y)'	System	16 Dec 2020 17:25:49

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-16T10:25:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4d3be6d2-da0c-4080-b695-2077222cb945'	System	16 Dec 2020 17:25:49
User entered 'No (N)'	System	16 Dec 2020 17:25:49

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-16T10:25:15', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4d3be6d2-da0c-4080-b695-2077222cb945'	System	16 Dec 2020 17:25:49
User entered 'No (N)'	System	16 Dec 2020 17:25:49

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-16T10:25:26', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4d3be6d2-da0c-4080-b695-2077222cb945'	System	16 Dec 2020 17:25:49
User entered 'Yes (Y)'	System	16 Dec 2020 17:25:49

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-16T10:25:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4d3be6d2-da0c-4080-b695-2077222cb945'	System	16 Dec 2020 17:25:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 17:25:49

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-16T10:25:39', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4d3be6d2-da0c-4080-b695-2077222cb945' User entered '16 Dec 2020 10:25:39'	System	16 Dec 2020 17:25:49
	System	16 Dec 2020 17:25:49



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-23T12:14:54', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '75bf81ec-b8b8-4703-ac8a-d063ea6ea2d9' User entered 'No (N)'	System	23 Dec 2020 19:15:07
	System	23 Dec 2020 19:15:07

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-23T12:14:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '75bf81ec-b8b8-4703-ac8a-d063ea6ea2d9' User entered 'No (N)'	System	23 Dec 2020 19:15:07
	System	23 Dec 2020 19:15:07

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-23T12:15:04', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '75bf81ec-b8b8-4703-ac8a-d063ea6ea2d9' User entered '23 Dec 2020 12:15:04'	System	23 Dec 2020 19:15:07
	System	23 Dec 2020 19:15:07

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-30T10:21:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '80c96a32-6dbe-4b81-a336-605a8b1fc57f' User entered 'No (N)'	System	30 Dec 2020 17:21:47
	System	30 Dec 2020 17:21:47

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-30T10:21:33', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '80c96a32-6dbe-4b81-a336-605a8b1fc57f' User entered 'No (N)'	System	30 Dec 2020 17:21:47
	System	30 Dec 2020 17:21:47

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2020-12-30T10:21:44', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '80c96a32-6dbe-4b81-a336-605a8b1fc57f' User entered '30 Dec 2020 10:21:44'	System	30 Dec 2020 17:21:47

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-15T09:05:04', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '2bb3f00e-aba3-4380-be60-eda52ba0865e' User entered 'No (N)'	System	15 Jan 2021 16:05:16
	System	15 Jan 2021 16:05:16

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-15T09:05:09', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '2bb3f00e-aba3-4380-be60-eda52ba0865e' User entered 'No (N)'	System	15 Jan 2021 16:05:16
	System	15 Jan 2021 16:05:16

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-15T09:05:14', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '2bb3f00e-aba3-4380-be60-eda52ba0865e' User entered '15 Jan 2021 09:05:14'	System	15 Jan 2021 16:05:16
	System	15 Jan 2021 16:05:16

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:05:03



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-22T13:10:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '39cf8bde-5367-4eec-9c34-5dff1c53bf82' User entered 'Yes (Y)'	System	22 Jan 2021 20:11:15
	System	22 Jan 2021 20:11:15

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-22T13:10:37', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '39cf8bde-5367-4eec-9c34-5dff1c53bf82'	System	22 Jan 2021 20:11:15
User entered 'No (N)'	System	22 Jan 2021 20:11:15

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-22T13:10:41', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '39cf8bde-5367-4eec-9c34-5dff1c53bf82' User entered 'No (N)'	System	22 Jan 2021 20:11:15
	System	22 Jan 2021 20:11:15

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-22T13:10:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '39cf8bde-5367-4eec-9c34-5dff1c53bf82' User entered 'Yes (Y)'	System	22 Jan 2021 20:11:15
	System	22 Jan 2021 20:11:15

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-22T13:10:59', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '39cf8bde-5367-4eec-9c34-5dff1c53bf82'	System	22 Jan 2021 20:11:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 20:11:15

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-22T13:11:05', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '39cf8bde-5367-4eec-9c34-5dff1c53bf82' User entered '22 Jan 2021 13:11:05'	System	22 Jan 2021 20:11:15
	System	22 Jan 2021 20:11:15

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-27T09:34:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '86c5d548-f396-411b-ad8c-d67f3d96428c' User entered 'No (N)'	System	27 Jan 2021 16:34:59
	System	27 Jan 2021 16:34:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-27T09:34:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '86c5d548-f396-411b-ad8c-d67f3d96428c' User entered 'No (N)'	System	27 Jan 2021 16:34:59
	System	27 Jan 2021 16:34:59

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-01-27T09:34:54', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '86c5d548-f396-411b-ad8c-d67f3d96428c' User entered '27 Jan 2021 09:34:54'	System	27 Jan 2021 16:34:59
	System	27 Jan 2021 16:34:59

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-03T08:11:02', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '7c37fe90-4acf-459c-b040-a265c0fa9c00' User entered 'No (N)'	System	03 Feb 2021 15:11:15
	System	03 Feb 2021 15:11:15



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-03T08:11:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '7c37fe90-4acf-459c-b040-a265c0fa9c00'	System	03 Feb 2021 15:11:15
User entered 'No (N)'	System	03 Feb 2021 15:11:15

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-03T08:11:13', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '7c37fe90-4acf-459c-b040-a265c0fa9c00' User entered '03 Feb 2021 08:11:13'	System	03 Feb 2021 15:11:15
	System	03 Feb 2021 15:11:15

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-10T07:59:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'bdc313d4-f3c4-4198-90e0-4e88e0ec6e79' User entered 'No (N)'	System	10 Feb 2021 14:59:51
	System	10 Feb 2021 14:59:51

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-10T07:59:43', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'bdc313d4-f3c4-4198-90e0-4e88e0ec6e79' User entered 'No (N)'	System	10 Feb 2021 14:59:51
	System	10 Feb 2021 14:59:51

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-10T07:59:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'bdc313d4-f3c4-4198-90e0-4e88e0ec6e79' User entered '10 Feb 2021 07:59:48'	System	10 Feb 2021 14:59:51
	System	10 Feb 2021 14:59:51



US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-20T18:18:49', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '349aad68-acb7-48e7-8593-323f128ac8a7' User entered 'No (N)'	System	21 Feb 2021 01:19:08
	System	21 Feb 2021 01:19:08

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-20T18:19:00', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '349aad68-acb7-48e7-8593-323f128ac8a7' User entered 'No (N)'	System	21 Feb 2021 01:19:08
	System	21 Feb 2021 01:19:08

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-20T18:19:05', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '349aad68-acb7-48e7-8593-323f128ac8a7' User entered '20 Feb 2021 18:19:05'	System	21 Feb 2021 01:19:08
	System	21 Feb 2021 01:19:08

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-25T18:33:09', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'bfc880f2-0d7c-4d03-842a-a1f74f93f1d5'	System	26 Feb 2021 01:41:57
User entered 'No (N)'	System	26 Feb 2021 01:41:57

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-25T18:33:13', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'bfc880f2-0d7c-4d03-842a-a1f74f93f1d5'	System	26 Feb 2021 01:41:57
User entered 'No (N)'	System	26 Feb 2021 01:41:57

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-02-25T18:33:17', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'bfc880f2-0d7c-4d03-842a-a1f74f93f1d5' User entered '25 Feb 2021 18:33:17'	System	26 Feb 2021 01:41:57

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-03T08:29:16', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '83c76525-c6a0-4062-ab9d-d56c34bf81c4' User entered 'Yes (Y)'	System	03 Mar 2021 15:30:30
	System	03 Mar 2021 15:30:30



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-03T08:29:22', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '83c76525-c6a0-4062-ab9d-d56c34bf81c4'	System	03 Mar 2021 15:30:30
User entered 'No (N)'	System	03 Mar 2021 15:30:30

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-03T08:29:47', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '83c76525-c6a0-4062-ab9d-d56c34bf81c4' User entered 'No (N)'	System	03 Mar 2021 15:30:30
	System	03 Mar 2021 15:30:30

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-03T08:29:58', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '83c76525-c6a0-4062-ab9d-d56c34bf81c4' User entered 'Yes (Y)'	System	03 Mar 2021 15:30:30
	System	03 Mar 2021 15:30:30

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-03T08:30:08', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '83c76525-c6a0-4062-ab9d-d56c34bf81c4'	System	03 Mar 2021 15:30:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Mar 2021 15:30:30

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-03T08:30:18', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '83c76525-c6a0-4062-ab9d-d56c34bf81c4' User entered '03 Mar 2021 08:30:18'	System	03 Mar 2021 15:30:30
	System	03 Mar 2021 15:30:30

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:05:03



US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-10T14:49:37', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a3fb1d89-99c6-4095-b7c7-721a44d8cf92'	System	10 Mar 2021 21:49:50
User entered 'No (N)'	System	10 Mar 2021 21:49:50

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-10T14:49:42', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a3fb1d89-99c6-4095-b7c7-721a44d8cf92'	System	10 Mar 2021 21:49:50
User entered 'No (N)'	System	10 Mar 2021 21:49:50

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-10T14:49:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a3fb1d89-99c6-4095-b7c7-721a44d8cf92' User entered '10 Mar 2021 14:49:45'	System	10 Mar 2021 21:49:50
	System	10 Mar 2021 21:49:50

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-17T08:34:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4725b333-8c49-4958-a186-0338fe6eca9a'	System	17 Mar 2021 14:34:56
User entered 'No (N)'	System	17 Mar 2021 14:34:56

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-17T08:34:49', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4725b333-8c49-4958-a186-0338fe6eca9a' User entered 'No (N)'	System	17 Mar 2021 14:34:56



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-17T08:34:53', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '4725b333-8c49-4958-a186-0338fe6eca9a' User entered '17 Mar 2021 08:34:53'	System	17 Mar 2021 14:34:56
	System	17 Mar 2021 14:34:56

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-26T12:00:41', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b547d1ed-5f7c-4043-87ec-93209fda54bb' User entered 'No (N)'	System	26 Mar 2021 18:00:51
	System	26 Mar 2021 18:00:51

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-26T12:00:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b547d1ed-5f7c-4043-87ec-93209fda54bb' User entered 'No (N)'	System	26 Mar 2021 18:00:51
	System	26 Mar 2021 18:00:51

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-26T12:00:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'b547d1ed-5f7c-4043-87ec-93209fda54bb' User entered '26 Mar 2021 12:00:48'	System	26 Mar 2021 18:00:51
	System	26 Mar 2021 18:00:51

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-02T12:01:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'c6ff191f-f412-4614-953b-a97b1336ef8d' User entered 'No (N)'	System	02 Apr 2021 18:01:43

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-02T12:01:31', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'c6ff191f-f412-4614-953b-a97b1336ef8d' User entered 'No (N)'	System	02 Apr 2021 18:01:43

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-02T12:01:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'c6ff191f-f412-4614-953b-a97b1336ef8d' User entered '02 Apr 2021 12:01:35'	System	02 Apr 2021 18:01:43
	System	02 Apr 2021 18:01:43

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-09T12:00:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a60eee16-0614-4056-b0e8-81367397460f' User entered 'No (N)'	System	09 Apr 2021 18:00:55
	System	09 Apr 2021 18:00:55

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-09T12:00:48', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a60eee16-0614-4056-b0e8-81367397460f'	System	09 Apr 2021 18:00:55
User entered 'No (N)'	System	09 Apr 2021 18:00:55

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-09T12:00:52', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'a60eee16-0614-4056-b0e8-81367397460f' User entered '09 Apr 2021 12:00:52'	System	09 Apr 2021 18:00:55
	System	09 Apr 2021 18:00:55

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-14T14:57:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ced542e-f7c7-49ed-9b0b-47ed08bee9ad' User entered 'No (N)'	System	14 Apr 2021 20:57:48
	System	14 Apr 2021 20:57:48

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-14T14:57:40', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ced542e-f7c7-49ed-9b0b-47ed08bee9ad' User entered 'No (N)'	System	14 Apr 2021 20:57:48
	System	14 Apr 2021 20:57:48



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-14T14:57:45', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '9ced542e-f7c7-49ed-9b0b-47ed08bee9ad' User entered '14 Apr 2021 14:57:45'	System	14 Apr 2021 20:57:48
	System	14 Apr 2021 20:57:48

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-21T06:26:19', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '94d8292d-a05a-4e45-a85c-9705c8f18944' User entered 'No (N)'	System	21 Apr 2021 12:26:31
	System	21 Apr 2021 12:26:31

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-21T06:26:24', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '94d8292d-a05a-4e45-a85c-9705c8f18944'	System	21 Apr 2021 12:26:31
User entered 'No (N)'	System	21 Apr 2021 12:26:31

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-21T06:26:29', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '94d8292d-a05a-4e45-a85c-9705c8f18944' User entered '21 Apr 2021 06:26:29'	System	21 Apr 2021 12:26:31
	System	21 Apr 2021 12:26:31

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-30T07:49:28', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'db3b4ad9-4a70-4e20-8995-eba42e4a2eba' User entered 'No (N)'	System	30 Apr 2021 13:49:40
	System	30 Apr 2021 13:49:40

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-30T07:49:32', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'db3b4ad9-4a70-4e20-8995-eba42e4a2eba' User entered 'No (N)'	System	30 Apr 2021 13:49:40

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-04-30T07:49:35', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: 'db3b4ad9-4a70-4e20-8995-eba42e4a2eba' User entered '30 Apr 2021 07:49:35'	System	30 Apr 2021 13:49:40
	System	30 Apr 2021 13:49:40

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:05:03



US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:05:03



US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:05:03



US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:05:03

US3332033

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:05:03

US3332033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:26

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:05:03



**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:05:03

**US3332033**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:09:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:05:03
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:05:03

US3332033

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:09:26**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-04T16:54:30', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3d21b555-b4da-4d2c-b911-caad088a85e4' User entered 'No (N)'	System	04 Mar 2021 23:54:38
	System	04 Mar 2021 23:54:38

US3332033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:09:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:26:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (71978F2B-F2DC-44EC-BE94-D15D0C7EEDAD)', Time: '2021-03-04T16:54:34', User OID: 'PatientReportedOutcome (US3332033)', ODM File OID: '3d21b555-b4da-4d2c-b911-caad088a85e4' User entered '04 Mar 2021 16:54:34'	System	04 Mar 2021 23:54:38
	System	04 Mar 2021 23:54:38

US3332033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:15

US3332033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '3 Nov 2020'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:15

US3332033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Contact Made (CONTACT MADE)'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:15



US3332033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered empty.	Ashley Bragg (b) (4)	09 Dec 2020 16:07:15

US3332033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:21

US3332033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:33
User entered 'I'	System	09 Dec 2020 16:07:21

US3332033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:36

US3332033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '8 Dec 2020'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:36

US3332033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Contact Made (CONTACT MADE)'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:36

US3332033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered empty.	Ashley Bragg (b) (4)	09 Dec 2020 16:07:36

US3332033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	09 Dec 2020 16:07:41



US3332033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'I'	System	09 Dec 2020 16:07:41

US3332033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	06 Jan 2021 19:23:14

US3332033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '6 Jan 2021'	Kenadie Hamblin (b) (4)	06 Jan 2021 19:23:14

US3332033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Contact Made (CONTACT MADE)'	Kenadie Hamblin (b) (4)	06 Jan 2021 19:23:14

US3332033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered empty.	Kenadie Hamblin (b) (4)	06 Jan 2021 19:23:14

US3332033

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	06 Jan 2021 19:23:19

US3332033

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'I'	System	06 Jan 2021 19:23:19

US3332033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Sean Hansen (b) (4)	05 Feb 2021 20:52:04



US3332033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '5 Feb 2021'	Sean Hansen (b) (4)	05 Feb 2021 20:52:04

US3332033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Contact Made (CONTACT MADE)'	Sean Hansen (b) (4)	05 Feb 2021 20:52:04

US3332033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered empty.	Sean Hansen (b) (4)	05 Feb 2021 20:52:04

US3332033

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	Sean Hansen (b) (4)	05 Feb 2021 20:52:13

US3332033

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'I'	System	05 Feb 2021 20:52:13

US3332033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	30 Mar 2021 17:38:31

US3332033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:47:51
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Visit out of window d/t subject's SAE' (Site from System).	Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 17:39:06
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Mar 2021 17:38:31
User entered '30 Mar 2021'	Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 17:38:31

US3332033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Clinic (Clinic)'	Ashley Bragg (b) (4)	30 Mar 2021 17:38:31



US3332033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'VISIT4'	System	30 Mar 2021 17:38:31

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '30 Mar 2021'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '10:46'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered '30 Mar 2021 10:46'	System	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '97.3' F	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Oral (Oral)'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 17:40:00



US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '73'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'bpm'	System	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '18'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'breaths/min'	System	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '121'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'mmHg'	System	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '60'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:00

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'mmHg'	System	30 Mar 2021 17:40:00



US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04

US3332033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04

US3332033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:06

US3332033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '30 Mar 2021'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:06

US3332033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:21

US3332033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '30 Mar 2021'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:21

US3332033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '10:54'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:21

US3332033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered '30 Mar 2021 10:54'	System	30 Mar 2021 17:40:21



US3332033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	30 Mar 2021 17:40:25

US3332033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:04
User entered 'I'	System	30 Mar 2021 17:40:25

US3332033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:30

US3332033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:30

US3332033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:30

US3332033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 16:46:30

US3332033

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:46:37

**US3332033**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:09:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 16:46:37



US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:19:46

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:19:46

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:19:46

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 16:19:46

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 22:18:40
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:35:14

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 06:35:24
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 22:19:11
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 22:18:40
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:37:40
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:35:14



US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:09:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered empty.	System	25 Jan 2021 16:20:01

US3332033

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:09:26**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered empty.	System	25 Jan 2021 16:20:01

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:29:22



US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:29:22

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '08:50'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:29:22

US3332033

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:09:26**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered '25 Jan 2021 08:50'	System	25 Jan 2021 16:29:22

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:30:32

US3332033

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:30:32

**US3332033**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:09:26**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '08:20'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:30:32

US3332033

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:09:26**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:42
User entered '25 Jan 2021 08:20'	System	25 Jan 2021 16:30:32

US3332033

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:09:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:23
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'Yes (Y)'	(b) (4) Lindsey Bevan (b) (4)	30 Oct 2020 23:08:58



US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 23:11:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 23:11:09
Data point term sent to Coder	System	30 Oct 2020 23:09:47
User entered 'WORSENING OF HYPERTENSION'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'No (N)'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'No (N)'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '11 Sep 2020'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '08:06'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:26**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 08:06'	System	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Yes (Y)'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43



US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
Query 'Per CDM-Per page 31 of CCGs,kindly consider to record end time of AE.' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:59:49
User opened query 'Per CDM-Per page 31 of CCGs,kindly consider to record end time of AE.' (Site from DM).		04 Nov 2020 06:57:59
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

Severity

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.	(b) (4), (b) (6)	30 Nov 2020 08:31:32
' (Site from DM).		
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.	(b) (4), (b) (6)	27 Nov 2020 19:50:18
' answered with 'per subject and investigator, doesn't interfere with daily activities correct as entered ' (Site from DM).		
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.	(b) (4), (b) (6)	24 Nov 2020 09:35:51
' (Site from DM).		
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'No (N)'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43



US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 23:10:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 23:10:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lindsey Bevan (b) (4)	30 Oct 2020 23:10:26
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 23:09:43
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43



US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 23:10:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 23:10:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lindsey Bevan (b) (4)	30 Oct 2020 23:10:26
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 23:09:43
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:07:09
Query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate.' answered with 'UPDATED RESPONSE.' (Site from DM).	Megan Grimmatt (b) (4)	04 Nov 2020 18:11:40
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Megan Grimmatt (b) (4)	04 Nov 2020 18:10:41
	(b) (4)	
User opened query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:59:05
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 23:10:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 23:10:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lindsey Bevan (b) (4)	30 Oct 2020 23:10:26
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 23:09:43
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:38
	(b) (4)	
Signature has been broken.	Kenadie Hamblin (b) (4)	29 Apr 2021 23:01:09
	(b) (4)	
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'I'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '0'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered empty.	Lindsey Bevan (b) (4)	30 Oct 2020 23:09:43



US3332033

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 23:09:43

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 23:09:43

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:47:08
DataPoint Verified.		27 Jan 2021 20:09:29
Un-reviewed for Safety.		27 Jan 2021 14:46:08
User entered empty; reason for change Per Query Resolution		27 Jan 2021 14:46:08
Reviewed for Safety.		26 Jan 2021 18:18:48
User entered 'USA-US202-2021-mRNA-1273-P301000004'		26 Jan 2021 18:18:45
User entered 'New'		26 Jan 2021 18:18:45

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 18:07:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 18:07:59
Data point term sent to Coder	System	16 Dec 2020 18:07:40
User entered 'Urinary tract infection'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'No (N)'	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '12 Dec 2020'	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21



US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User entered empty.	System	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'No (N)' reason for change: New Information	Kenadie Hamblin (b) (4) (b) (4)	06 Jan 2021 19:24:41
User entered 'Yes (Y)'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '19 Dec 2020' reason for change: New Information	Kenadie Hamblin (b) (4) (b) (4)	06 Jan 2021 19:24:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User entered empty.	System	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error		27 Jan 2021 01:02:42
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error		25 Jan 2021 16:34:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		16 Dec 2020 18:07:21
	Ashley Bragg (b) (4) (b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	27 Jan 2021 16:25:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	27 Jan 2021 16:23:49
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	27 Jan 2021 01:02:59
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	27 Jan 2021 01:02:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 01:02:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:34:26
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21



US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21



US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0' reason for change: Data Entry Error	Ashley Bragg (b) (4)	27 Jan 2021 16:25:04
User entered '1' reason for change: Data Entry Error	(b) (4) Ashley Bragg (b) (4)	27 Jan 2021 16:23:49
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Jan 2021 01:02:59
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:34:26
User entered '0'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 18:07:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 18:07:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:31
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 18:07:21
User entered empty.	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'l'	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	Ashley Bragg (b) (4)	16 Dec 2020 18:07:21



US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Kenadie Hamblin (b) (4) (b) (4)	06 Jan 2021 19:24:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Jan 2021 16:25:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	27 Jan 2021 16:25:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Jan 2021 16:23:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 01:02:42
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 16:50:49
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Jan 2021 16:50:49
User entered 'SUBJECT SUDDENTLY FAINTED WHILE HOME. AMBULANCE CALLED AND BP REPORTED AROUND 80/40. TRANSMITTED TO ER AND TREATED FOR UTI WITH IV ANTIBIOTICS AND DISCHARGED HOME APRX 4 HOURS LATER ON PO ANTIBIOTICS' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:50:49
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 16:34:26
User entered empty.	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User entered '0'	System	27 Jan 2021 16:25:04
User entered '1'	System	27 Jan 2021 16:23:49
User entered '0'	System	27 Jan 2021 01:02:42
User entered '1'	System	25 Jan 2021 16:34:26
User entered '0'	System	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52
User entered '1'	System	16 Dec 2020 18:07:21

US3332033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:33:52

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:47:46
User entered 'USA-US202-2021-mRNA-1273-P301000004'	(b) (4), (b) (6)	27 Jan 2021 14:47:34

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 01:05:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 01:05:53
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 01:05:17
Coding entries removed.	(b) (4), (b) (6)	27 Jan 2021 01:05:10
	(b) (4), (b) (6)	
User entered 'SYNCOPE' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 01:05:10
	(b) (4), (b) (6)	
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope hypotensive - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 21:13:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 21:13:54
	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 16:48:03
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 16:47:10
	(b) (4), (b) (6)	
User entered 'SYNCOPE SECONDARY TO HYPOTENSION' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:47:10
	(b) (4), (b) (6)	
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 16:44:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 16:44:54
	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 16:44:00
User entered 'SYNCOPE'	(b) (4), (b) (6)	25 Jan 2021 16:43:24
	(b) (4), (b) (6)	



US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:48:36
User entered '18 Dec 2020'		25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24
	(b) (4), (b) (6)	

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:26**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	25 Jan 2021 16:48:36
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	25 Jan 2021 16:48:23
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:48:23
User entered '18 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 16:43:24



US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 01:05:10
User entered 'Grade 3/Severe (Grade 3/Severe)'		25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Yes (Y)' reason for change: Data Entry Error		27 Jan 2021 01:05:10
User entered 'No (N)'		25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24



US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '1' reason for change: Data Entry Error		27 Jan 2021 01:05:10
User entered '0'		25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 16:43:24



US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:43:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 16:43:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:43:36
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:43:24
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 01:31:02
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Jan 2021 16:43:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:43:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Jan 2021 16:43:24
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '1' reason for change: Data Entry Error		27 Jan 2021 01:31:02
User entered '0'		25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:01:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'no relevant records ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:44:32
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 00:31:15
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:29:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'The requested records were emailed.' (Site from Safety).	Sean Hansen (b) (4)	08 Feb 2021 22:18:49
	(b) (4)	
User closed query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 17:37:12
Query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'NOT DONE' (Site from Safety).	Ashley Bragg (b) (4)	03 Feb 2021 17:19:02
	(b) (4)	
DataPoint Un-verified.	Ashley Bragg (b) (4)	03 Feb 2021 17:18:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SAE INITIALLY REPORTED AS UTI BUT UPON RECEIPT OF MEDICAL RECORDS ON 25JAN2021, PI CHANGED SAE TO SYNCOPE RECORDS INDICATE EVENT MAY BE SECONDARY TO VIAGRA USE WHICH THE SUBJECT NEVER REPORTED TAKING BUT DID CONFIRM HE HAS TAKEN FOR YEARS. SUBJECT SUDDENTLY FAINTED WHILE HOME. AMBULANCE CALLED AND BP REPORTED AROUND "80/40." TRANSMITTED TO ER AND TREATED FOR UTI WITH IV ANTIBIOTICS AND DISCHARGED HOME APRX 4 HOURS LATER ON PO ANTIBIOTICS. COVID TESTING NOT DONE.' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	03 Feb 2021 17:18:55
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Feb 2021 15:12:18
User opened query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Feb 2021 15:12:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 20:09:29



US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SAE INITIALLY REPORTED AS UTI BUT UPON RECEIPT OF MEDICAL RECORDS ON 25JAN2021, PI CHANGED SAE TO SYNCOPE RECORDS INDICATE EVENT MAY BE SECONDARY TO VIAGRA USE WHICH THE SUBJECT NEVER REPORTED TAKING BUT DID CONFIRM HE HAS TAKEN FOR YEARS. SUBJECT SUDDENTLY FAINTED WHILE HOME. AMBULANCE CALLED AND BP REPORTED AROUND "80/40." TRANSMITTED TO ER AND TREATED FOR UTI WITH IV ANTIBIOTICS AND DISCHARGED HOME APRX 4 HOURS LATER ON PO ANTIBIOTICS' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	27 Jan 2021 16:34:54
User entered 'SAE INITIALL REPORTED AS UTI BUT UPON RECEIPT OF MEDICAL RECORDS, PI CHANGED SAE TO SYNCOPE RECORDS INDICATE EVENT MAY BE SECONDARY TO VIAGRA USE WHICH THE SUBJECT NEVER REPORTED TAKING BUT DID CONFIRM HE HAS TAKEN FOR YEARS. SUBJECT SUDDENTLY FAINTED WHILE HOME. AMBULANCE CALLED AND BP REPORTED AROUND "80/40." TRANSMITTED TO ER AND TREATED FOR UTI WITH IV ANTIBIOTICS AND DISCHARGED HOME APRX 4 HOURS LATER ON PO ANTIBIOTICS' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 01:18:43
User entered 'SUBJECT SUDDENTLY FAINTED WHILE HOME. AMBULANCE CALLED AND BP REPORTED AROUND 80/40. TRANSMITTED TO ER AND TREATED FOR UTI WITH IV ANTIBIOTICS AND DISCHARGED HOME APRX 4 HOURS LATER ON PO ANTIBIOTICS' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 01:05:10
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Jan 2021 16:43:24

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 01:05:10
User entered '0'	System	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 16:43:24

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:53:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:53:49
Data point term sent to Coder	System	25 Jan 2021 16:53:10
User entered 'urinary tract infection'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38



US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '18 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User entered empty.	System	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
DataPoint Un-verified.	Sean Hansen (b) (4)	10 Feb 2021 16:26:22
User entered 'No (N)' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Feb 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
DataPoint Un-verified.	Sean Hansen (b) (4)	10 Feb 2021 16:26:22
User entered '6 Feb 2021' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Feb 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User entered empty.	System	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38



US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:29
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:52:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 16:52:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:52:45
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 16:52:38
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38



US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered 'l'	(b) (4), (b) (6)	25 Jan 2021 16:52:38



US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
DataPoint Un-verified.	Sean Hansen (b) (4)	10 Feb 2021 16:26:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Feb 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:09:29
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User entered '0'	System	25 Jan 2021 16:52:45

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05
User entered 'I'	System	25 Jan 2021 16:52:38

US3332033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:05

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:35:35
User entered		
'USA-US202-2021-mRNA-1273-P301000005'	System	01 Mar 2021 18:16:51
User entered 'New'	(b) (4), (b) (6)	01 Mar 2021 18:16:51



US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non ST segment elevation myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 18:12:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 18:12:06
User signature succeeded.	James Peterson (b) (4) (b) (4)	31 Mar 2021 15:16:28
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: ST segment elevation myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:10:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:10:41
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'For coding purposes, please provide more information for term CARDIAC EVENT. Please update the term with your response.' (Site from Coder).	(b) (4), (b) (6)	08 Mar 2021 15:55:44
Data point term sent to Coder	System	05 Mar 2021 00:49:07
Query 'For coding purposes, please provide more information for term CARDIAC EVENT. Please update the term with your response.' answered with 'updated' (Site from Coder).	(b) (4), (b) (6)	05 Mar 2021 00:48:33
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 00:48:18
User entered 'Non-ST Elevation acute myocardial Infarction' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 00:48:18
User coded data point as SOC: Cardiac disorders, HLT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac disorders NEC, PT: Acute cardiac event, LLT: Acute cardiac event - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:05:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:05:43
User opened query 'For coding purposes, please provide more information for term CARDIAC EVENT. Please update the term with your response.' (Site from Coder).	(b) (4), (b) (6)	02 Mar 2021 18:01:46

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	26 Feb 2021 21:10:28
User entered 'CARDIAC EVENT'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date for non-ST elevation acute myocardial infarction, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 10:07:25
Query 'PV Query: Please provide the event end date for non-ST elevation acute myocardial infarction, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available' answered with 'THERE IS AN END DATE ENTERED OF 3.5.21 PLEASE CLARIFY' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:48:48
User opened query 'PV Query: Please provide the event end date for non-ST elevation acute myocardial infarction, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 18:44:57
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 21:09:54
	(b) (4), (b) (6)	

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:09:26**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:09:54



US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
DataPoint Un-verified.	(b) (4)	09 Apr 2021 22:17:43
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 22:17:43
User entered 'No (N)' reason for change: Data Entry Error		09 Apr 2021 22:17:43
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
DataPoint Un-verified.	(b) (4)	09 Apr 2021 22:17:43
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 22:17:43
User entered '05 Mar 2021' reason for change: Data Entry Error		09 Apr 2021 22:17:43
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 14:52:01
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	30 Mar 2021 14:52:01
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Mar 2021 23:53:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		05 Mar 2021 14:40:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		05 Mar 2021 14:30:25
User entered empty.		26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 21:09:54
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date for non-ST elevation acute myocardial infarction, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:12:53
User opened query 'PV Query: Please provide the event end date for non-ST elevation acute myocardial infarction, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).		08 Apr 2021 13:09:26
Query 'PV Query: And end date for the event of Worsening of Coronary Artery Disease is reported as 05 Mar 2021 but the outcome for that event remains Not Recovered/Not Resolved. Please reconcile. ' canceled (Site from Safety).		08 Apr 2021 13:08:49
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		08 Apr 2021 13:08:45
Query ' . PV Query: The outcome of the event 'non-ST elevation acute myocardial infarction' was reported as recovered, however the end date is missing. Kindly confirm the event end date. ' canceled (Site from Safety).		29 Mar 2021 22:22:08
User opened query ' . PV Query: The outcome of the event 'non-ST elevation acute myocardial infarction' was reported as recovered, however the end date is missing. Kindly confirm the event end date. ' (Site from Safety).		29 Mar 2021 22:21:01

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: And end date for the event of Worsening of Coronary Artery Disease is reported as 05 Mar 2021 but the outcome for that event remains Not Recovered/Not Resolved. Please reconcile. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 22:17:01
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:26:41
User entered empty.	System	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error		05 Mar 2021 00:48:18
User entered 'Grade 3/Severe (Grade 3/Severe)'		26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 21:09:54



US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 06:01:10
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject has not yet been discharged ' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 21:03:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 00:57:12
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	01 Mar 2021 04:27:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'AE ONGOING AND ICU QUESTION IS ANSWERED ' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 21:11:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	26 Feb 2021 21:09:54
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '26 Feb 2021' reason for change: Data Entry Error		05 Mar 2021 00:57:12
User entered '25 Feb 2021'		26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	25 Mar 2021 16:59:26
User closed query 'Per source, Subject discharged on 27Feb21, please verify.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 16:59:17
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		24 Mar 2021 10:43:09
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'submitted ' (Site from Safety).		23 Mar 2021 23:53:11
Query 'Per source, Subject discharged on 27Feb21, please verify.' answered with 'updated' (Site from CRA).		19 Mar 2021 14:26:04
DataPoint Un-verified.		19 Mar 2021 14:25:55
User entered '27 Feb 2021' reason for change: Data Entry Error		19 Mar 2021 14:25:55
DataPoint Verified.		11 Mar 2021 23:19:06
User opened query 'Per source, Subject discharged on 27Feb21, please verify.' (Site from CRA).		11 Mar 2021 23:15:07
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		11 Mar 2021 20:28:34

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:40:34
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).		05 Mar 2021 14:40:13
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.		05 Mar 2021 14:31:40
' (Site from Safety).		
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		05 Mar 2021 14:29:58
User entered empty.		26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	08 Mar 2021 21:04:16
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	08 Mar 2021 21:04:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 21:04:16
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	08 Mar 2021 18:56:47
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 18:56:47
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 21:09:54



US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 21:09:54
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:19:06
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).		05 Mar 2021 14:40:21
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		05 Mar 2021 14:30:51
User entered '0'		26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 21:09:54



US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User closed query 'PV Query: Please provide the final event outcome for non-ST elevation acute myocardial infarction, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:52:18
Query 'PV Query: Please provide the final event outcome for non-ST elevation acute myocardial infarction, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).		09 Apr 2021 22:18:01
Signature has been broken.		09 Apr 2021 22:17:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		09 Apr 2021 22:17:43
User opened query 'PV Query: Please provide the final event outcome for non-ST elevation acute myocardial infarction, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).		08 Apr 2021 13:09:53
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:46:58

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Final event outcome will be updated once resolved. Will not keep query open due to DBL 3/31/21 and query metrics.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 14:53:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error		30 Mar 2021 14:52:01
DataPoint Un-verified.		23 Mar 2021 23:53:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		23 Mar 2021 23:53:42
DataPoint Verified.		11 Mar 2021 23:19:06
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		11 Mar 2021 20:27:11
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).		05 Mar 2021 14:40:30
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		05 Mar 2021 14:30:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'		26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 21:09:54
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'PV Query: Please provide any additional treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:47:01
Query 'PV Query: Please provide any additional treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medical intervention is the stent placement and the CABG (coronary artery bypass grafting) ' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 15:00:33
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 14:59:46
User entered 'SUBJECT ADMITTED TO HOSPITAL AND STENT PLACEMENT OCCURRED ON 26 FEB 2021 THEN UNDERWENT CABG ON 01 MAR 2021' reason for change: Data Entry Error		30 Mar 2021 14:59:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		24 Mar 2021 10:43:27
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 10:43:23

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'submitted' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 23:54:33
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No evidence of COVID-19 testing in the medical records we have received.' (Site from Safety).	Kenadie Hamblin (b) (4)	23 Mar 2021 17:42:33
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:30:23
User opened query 'PV Query: Please provide any additional treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:27:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:25:58
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:40:26

PRODUCTION RELEASE (v12.003  
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1900 of 2689

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:29:40
User entered 'SUBJECT ADMITTED TO HOSPITAL AND STENT PLACEMENT OCCURED, underwent CABG 3.1.21' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 00:48:18
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 21:10:58
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Feb 2021 21:10:58
User entered 'SUBJECT ADMITTED TO HOSPITAL AND STENT PLACEMENT OCCURED, ANTICIPATING OPEN HEART SURGERY ASAP' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 21:10:58
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 21:09:54
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 21:09:54

US3332033

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 09 Jun 2021 17:09:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 21:09:54



**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 21:09:54

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:47:08
DataPoint Verified.		11 Mar 2021 23:19:06
User entered 'USA-US202-2021-mRNA-1273-P301000005'		05 Mar 2021 15:36:30

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease aggravated - version MedDRA\23.0.	Coder Import (b) (4)	05 Mar 2021 00:57:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Mar 2021 00:57:44
Data point term sent to Coder	System	05 Mar 2021 00:57:07
User entered 'worsening of coronary artery disease'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'Per source, Start date corrected to 25Feb21, Please verify.' (Site from CRA).	(b) (4)	30 Mar 2021 19:24:26
Query 'Per source, Start date corrected to 25Feb21, Please verify.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:03:21
User entered '25 Feb 2021' reason for change: Data Entry Error		30 Mar 2021 15:02:47
DataPoint Un-verified.		11 Mar 2021 23:19:28
DataPoint Verified.		11 Mar 2021 23:19:06
User opened query 'Per source, Start date corrected to 25Feb21, Please verify.' (Site from CRA).		11 Mar 2021 22:55:19
Query 'Per source, date corrected to 28Feb21, Please verify.' canceled (Site from CRA).		11 Mar 2021 22:54:40
User opened query 'Per source, date corrected to 28Feb21, Please verify.' (Site from CRA).		11 Mar 2021 22:53:36
User entered '26 Feb 2021'		05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	



**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:09:26**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 10:07:33
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' answered with 'end date is provided please clarify' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:59:43
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 18:45:44
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'No (N)' reason for change: Data Entry Error		11 Mar 2021 16:56:31
User entered 'Yes (Y)'		05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	30 Mar 2021 15:02:47
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Mar 2021 15:02:47
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Mar 2021 16:56:31
User entered '5 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 16:56:31
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:35:53
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:32:04
User entered empty.	System	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:56:23



US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 05:37:24
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'data entered ' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 00:56:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 00:56:23
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'PV Query: Please consider updating admission date to 01Mar2021, as this was the date reported the subject underwent cardiac surgery. ' (Site from Safety).	(b) (4)	30 Mar 2021 17:47:16
Query 'PV Query: Please consider updating admission date to 01Mar2021, as this was the date reported the subject underwent cardiac surgery. ' answered with 'Admission date to the hospital was 2/28/21 per hospital records. Will not revise.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 15:04:24
User opened query 'PV Query: Please consider updating admission date to 01Mar2021, as this was the date reported the subject underwent cardiac surgery. ' (Site from Safety).		29 Mar 2021 22:20:00
DataPoint Verified.		11 Mar 2021 23:19:06
User entered '28 Feb 2021'		05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4)	30 Mar 2021 17:47:18
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'Discharge date is entered' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 15:04:42
DataPoint Verified.		11 Mar 2021 23:19:06
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).		11 Mar 2021 20:33:45
User entered '5 Mar 2021' reason for change: Data Entry Error		11 Mar 2021 16:56:31
User entered empty.		05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	



US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query '. PV Query: The outcome of the event 'non-ST elevation acute myocardial infarction' was reported as recovered, however the end date is missing. Kindly confirm the event end date. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:47:25
User closed query 'PV Query: And end date for the event of Worsening of Coronary Artery Disease is reported as 05 Mar 2021 but the outcome for that event remains Not Recovered/Not Resolved. Please reconcile.' (Site from Safety).		30 Mar 2021 17:47:23
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		30 Mar 2021 17:47:21
Query '. PV Query: The outcome of the event 'non-ST elevation acute myocardial infarction' was reported as recovered, however the end date is missing. Kindly confirm the event end date. ' answered with 'Updated' (Site from Safety).		30 Mar 2021 15:06:18
Query 'PV Query: And end date for the event of Worsening of Coronary Artery Disease is reported as 05 Mar 2021 but the outcome for that event remains Not Recovered/Not Resolved. Please reconcile.' answered with 'Updated' (Site from Safety).		30 Mar 2021 15:05:32
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Updated' (Site from Safety).		30 Mar 2021 15:05:05
DataPoint Un-verified.		30 Mar 2021 15:02:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		30 Mar 2021 15:02:47
User opened query '. PV Query: The outcome of the event 'non-ST elevation acute myocardial infarction' was reported as recovered, however the end date is missing. Kindly confirm the event end date. ' (Site from Safety).		29 Mar 2021 22:21:37



US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: And end date for the event of Worsening of Coronary Artery Disease is reported as 05 Mar 2021 but the outcome for that event remains Not Recovered/Not Resolved. Please reconcile.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 14:06:00
		11 Mar 2021 23:19:06
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		11 Mar 2021 20:32:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'		05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:56:23
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:47:33
User closed query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		30 Mar 2021 17:47:31
User closed query 'PV Query: Please provide any additional treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		30 Mar 2021 17:47:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		30 Mar 2021 17:47:27
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'not performed' (Site from Safety).		30 Mar 2021 15:11:45

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
Query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'this was completed on 23 mar 2021' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 15:10:56
Query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'this was completed on 23 mar 2021' (Site from Safety).		30 Mar 2021 15:10:42
Query 'PV Query: Please provide any additional treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medical intervention and surgical treatments indicated in narrative. Concomitant medications have been entered under the concomitant medication page' (Site from Safety).		30 Mar 2021 15:10:05
DataPoint Verified.		11 Mar 2021 23:19:06
User opened query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		11 Mar 2021 20:34:11

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:33:19
User opened query 'PV Query: Please provide any additional treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		11 Mar 2021 20:32:48
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		11 Mar 2021 20:31:33
User entered 'SUBJECT INITIALLY HOSPITALIZED 2/26/21 WITH MI, STENT PLACED BUT SURGICAL INTERVENTION WAS RECOMMENDED. SUBJECT WANTED TO HAVE SURGERY IN HOMETOWN SO HE WAS DISCHARGED HOME 2/27/21 WITH A SCHEDULED CARDIAC SURGERY SCHEDULED FOR 3.1.21. SURGERY PERFORMED WITHOUT COMPLICATIONS. SUBJECT CURRENTLY STILL HOSPITALIZED RECOVERING WELL. Subject discharged 3.5.21, unable to travel for 1 mo' reason for change: Data Entry Error		11 Mar 2021 16:56:31
User entered 'Subject initially hospitalized 2/26/21 with MI, stent placed but surgical intervention was recommended. Subject wanted to have surgery in hometown so he was discharged home 2/27/21 with a scheduled cardiac surgery scheduled for 3.1.21. surgery performed without complications. Subject currently still hospitalized recovering well'		05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 00:56:23

US3332033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:09:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 00:56:23

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:09:26**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 00:56:23



US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 00:59:44
	(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 00:59:44
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 00:59:08
User entered 'hiatal hernia'	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '28 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:09:26**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 00:58:13



US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13



US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 21:05:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 21:05:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 21:05:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 00:58:13
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13



US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 21:05:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 21:05:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 21:05:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 00:58:13
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 21:05:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 21:05:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 21:05:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 00:58:13
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:19:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	

US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
DataPoint Verified.	(b) (4)	11 Mar 2021 23:19:06
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 00:58:13
	(b) (4), (b) (6)	



US3332033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 00:58:13

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:09:26**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 00:58:13

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'Per MM, please update the AE term to specify cause or medical diagnosis ' (Site from DM).	(b) (4)	31 Mar 2021 14:51:09
User closed query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	(b) (4), (b) (6)	
Query 'Per MM, please confirm if the subject was evaluated for COVID-19' answered with 'none of the records or the patient indicate that he was swabbed or tested in any manner for COVID-19' (Site from DM).		
Query 'Per MM, please update the AE term to specify cause or medical diagnosis ' answered with 'This is the medical diagnosis' (Site from DM).		
User opened query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).		
User opened query 'Per MM, please update the AE term to specify cause or medical diagnosis ' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pulmonary effusion - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 01:00:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 01:00:41
Data point term sent to Coder	System	12 Mar 2021 16:07:17
User entered 'Pulmonary Effusions'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '26 Feb 2021'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 16:06:24

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 16:06:24

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	12 Mar 2021 16:06:38
User entered '1' reason for change: Data Entry Error	Ashley Bragg (b) (4)	12 Mar 2021 16:06:38
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	12 Mar 2021 16:06:24
User entered '0'	Ashley Bragg (b) (4) (b) (4)	12 Mar 2021 16:06:24

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:06:24
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 16:06:24

US3332033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:09:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 16:06:24

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 16:10:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 16:10:46
Data point term sent to Coder	System	12 Mar 2021 16:09:20
User entered 'Anemia'	Ashley Bragg (b) (4) (b) (4)	12 Mar 2021 16:08:36

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '26 Feb 2021'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 16:08:36

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 16:08:36

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

**Folder:** Adverse Events

**Form:** Adverse Events (10)

**Generated On:** 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	12 Mar 2021 16:08:36

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'I'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	12 Mar 2021 16:08:36

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Mar 2021 16:08:36
	(b) (4)	

US3332033

**Folder:** Adverse Events

**Form:** Adverse Events (10)

**Generated On:** 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 16:08:36

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:09:26**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 16:08:36

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Mar 2021 08:02:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:02:22
Data point term sent to Coder	System	30 Mar 2021 17:46:26
User entered 'Lower extremity peripheral edema'	Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 17:45:55

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '1 Mar 2021'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:45:55

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:45:55

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	



US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'I'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:09:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	31 Mar 2021 15:16:28
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 17:45:55
	(b) (4)	

US3332033

**Folder:** Adverse Events

**Form:** Adverse Events (11)

**Generated On:** 09 Jun 2021 17:09:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 17:45:55

**US3332033**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:09:26**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 17:45:55



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 17:09:26**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:23
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:19:08
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:03:39

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:06:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:06:56
Data point term sent to Coder	System	08 Sep 2020 15:05:46
User entered 'Atorvastatin'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Hypercholesterolemia'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '40'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'once daily (QD)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'un UNK 2017'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
DataPoint Un-verified.		10 Mar 2021 03:25:08
User entered 'No (N)' reason for change: Data Entry Error		10 Mar 2021 03:25:08
DataPoint Verified.		27 Jan 2021 20:18:58
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
DataPoint Un-verified.		10 Mar 2021 03:25:08
User entered '26 Feb 2021' reason for change: Data Entry Error		10 Mar 2021 03:25:08
DataPoint Verified.		27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:04:55



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User entered '1'	System	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User entered '1'	System	08 Sep 2020 15:04:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:29
User entered '804 (804)'	System	08 Sep 2020 15:04:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:07:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:07:46
Data point term sent to Coder	System	08 Sep 2020 15:06:49
User entered 'Metoprolol'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Hypertension'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '25'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'once daily (QD)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'un UNK 2017'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Un-verified.	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:50:28
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:50:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:05:53
	(b) (4)	



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Un-verified.	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:50:28
User entered '26 Feb 2021' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:50:28
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:05:53
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4)	08 Sep 2020 15:05:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User entered '1'	System	08 Sep 2020 15:05:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User entered '1'	System	08 Sep 2020 15:05:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:35
User entered '804 (804)'	System	08 Sep 2020 15:05:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:09:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:09:43
Data point term sent to Coder	System	08 Sep 2020 15:08:51
User entered 'Losartan'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Hypertension'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '100'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'once daily (QD)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'un UNK 2017'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:07:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:57:45
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:07:55
	(b) (4)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 16:57:45
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4)	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User entered '1'	System	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User entered '1'	System	08 Sep 2020 15:07:55

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:46
User entered '804 (804)'	System	08 Sep 2020 15:07:55

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:10:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:10:47
Data point term sent to Coder	System	08 Sep 2020 15:09:52
User entered 'Clopidogrel'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:29:40
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' answered with '.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 20:26:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:26:31
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:56:36
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Cardiac Prophylaxis'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '75'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'once daily (QD)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'un UNK 2017'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)' reason for change: Data Entry Error	Colby Bostock (b) (4)	02 Oct 2020 19:05:00
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '30 Sep 2020' reason for change: New Information	Colby Bostock (b) (4)	02 Oct 2020 19:05:00
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:09:07

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4)	08 Sep 2020 15:09:07

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User entered '1'	System	08 Sep 2020 15:09:07

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User entered '1'	System	08 Sep 2020 15:09:07



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:56
User entered '804 (804)'	System	08 Sep 2020 15:09:07

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:11:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:11:31
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 15:09:54
User entered 'Aspirin'	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Cardiac Prophylaxis'	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '81'	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'once daily (QD)'	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'un UNK 2017'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ty Henry (b) (4)	08 Sep 2020 15:09:53
	(b) (4)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:09:53



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:09:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:09:53

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:09:53

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:13:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:13:16
Data point term sent to Coder	System	08 Sep 2020 15:11:55
User entered 'Metformin'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Prediabetes'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '500'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:11:13



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:11:13

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'once daily (QD)'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'un UNK 2017'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Yes (Y)'	Ty Henry (b) (4)	08 Sep 2020 15:11:13
	(b) (4)	



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:11:13

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	08 Sep 2020 15:11:13

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:11:13

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:11:13

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 15:11:13

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 16:09:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 16:09:54
Data point term sent to Coder	System	09 Dec 2020 16:09:11
User entered 'Influenza vaccine'	Ashley Bragg (b) (4) (b) (4)	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Influenza prophylaxis'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'l'	Ashley Bragg (b) (4) (b) (4)	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Other (OTHER)'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'injection'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'once (ONCE)'	Ashley Bragg (b) (4) (b) (4)	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ashley Bragg (b) (4) (b) (4)	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Intramuscular (INTRAMUSCULAR)'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '17 Nov 2020'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ashley Bragg (b) (4) (b) (4)	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '17 Nov 2020'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ashley Bragg (b) (4)	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User entered empty.	System	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User entered empty.	System	09 Dec 2020 16:09:05

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:12
User entered empty.	System	09 Dec 2020 16:09:05

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEFALOXIN [CEFALOXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Dec 2020 18:11:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Dec 2020 18:11:23
Data point term sent to Coder	System	16 Dec 2020 18:09:41
User entered 'Cephalexin'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Urinary tract infection'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:26**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '500'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'four times daily (QID)'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '12 Dec 2020'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:06:17
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated per query' (Site from DM).	Sean Hansen (b) (4) (b) (4)	26 Jan 2021 21:39:51
User entered 'No (N)' reason for change: Data Entry Error	Sean Hansen (b) (4) (b) (4)	26 Jan 2021 21:39:42
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:43:34
User entered 'Yes (Y)'	Ashley Bragg (b) (4) (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '19 Dec 2020' reason for change: Data Entry Error	Sean Hansen (b) (4)	26 Jan 2021 21:39:42
User entered empty.	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	Ashley Bragg (b) (4)	16 Dec 2020 18:09:03

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User entered '4'	System	16 Dec 2020 18:09:03

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User entered '1'	System	16 Dec 2020 18:09:03



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:20
User entered '804 (804)'	System	16 Dec 2020 18:09:03

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN, PRODUCTSYNONYM: CIPRO [CIPROFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:55:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:55:51
Data point term sent to Coder	System	25 Jan 2021 16:55:14
User entered 'CIPRO'	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'URINARY TRACT INFECTION'	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '500'	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Jan 2021 20:18:58
		25 Jan 2021 16:55:00

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	27 Jan 2021 20:18:58
		25 Jan 2021 16:55:00



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Jan 2021 20:18:58
		25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '20 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	11 Mar 2021 23:34:17
DataPoint Un-verified.	Sean Hansen (b) (4)	10 Feb 2021 16:26:59
User entered 'No (N)' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Feb 2021 16:26:59
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
DataPoint Un-verified.	Sean Hansen (b) (4)	10 Feb 2021 16:26:59
User entered '6 Feb 2021' reason for change: Data Entry Error	Sean Hansen (b) (4)	10 Feb 2021 16:26:59
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:00

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:55:00



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User entered '2'	System	25 Jan 2021 16:55:00

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User entered '1'	System	25 Jan 2021 16:55:00

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:06
User entered '804 (804)'	System	25 Jan 2021 16:55:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 23:24:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 23:24:03
	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 16:56:14
User entered 'TAMSULOSIN'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 4). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 05:30:58
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 4). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'correct as entered. Subject given Keflex for UTI (AE #4) PRESCRIBED Tamsulosin to prevent future UTIs' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:47:55
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 4). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:04:08
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'UTI PROPHYLAXIS'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered '0.4'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Jan 2021 16:55:57
	(b) (4), (b) (6)	



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered '20 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 16:55:57
	(b) (4), (b) (6)	

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 16:55:57



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:09:26**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:55:57

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 16:55:57

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 16:55:57

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 16:55:57

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 16:58:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 16:58:58
Data point term sent to Coder	System	25 Jan 2021 16:58:15
User entered 'LOSARTAN'	(b) (4), (b) (6)	25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 20:18:58
		25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered 'HYPERTENSION'	(b) (4), (b) (6)	25 Jan 2021 16:57:26



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered '50'	(b) (4), (b) (6)	25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Jan 2021 20:18:58
		25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
		25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Jan 2021 20:18:58
		25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered '12 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 16:57:26



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	(b) (4), (b) (6)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	1 Mar 2021 23:34:17
DataPoint Un-verified.		0 Mar 2021 03:28:13
User entered 'No (N)' reason for change: Data Entry Error		0 Mar 2021 03:28:13
DataPoint Verified.		7 Jan 2021 20:18:58
User entered 'Yes (Y)'		5 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Mar 2021 23:34:17
DataPoint Un-verified.		10 Mar 2021 03:28:13
User entered '26 Feb 2021' reason for change: Data Entry Error		10 Mar 2021 03:28:13
DataPoint Verified.		27 Jan 2021 20:18:58
User entered empty.		25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 16:57:26

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User entered '1'	System	25 Jan 2021 16:57:26

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User entered '1'	System	25 Jan 2021 16:57:26

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:30
User entered '804 (804)'	System	25 Jan 2021 16:57:26

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL, PRODUCTSYNONYM: VIAGRA [SILDENAFIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 01:21:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 01:21:58
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 01:21:20
User entered 'VIAGRA'	(b) (4), (b) (6)	27 Jan 2021 01:21:18



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 04:37:14
Query 'Per DM CLR: Please note that there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'added to med hx' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:17:17
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:05:08
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'ERECTILE DYSFUNCTION'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered '100'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Jan 2021 01:21:18



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User entered 'UN UNK 2017'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	27 Jan 2021 20:18:58
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:18:58
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 01:22:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 01:22:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 01:22:03
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 01:21:18
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 01:21:18

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 01:21:18

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 01:21:18



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 01:21:18

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 10:12:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	29 Jan 2021 10:12:15
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:53
Data point term sent to Coder	System	28 Jan 2021 16:40:47
User entered 'ROCEPHIN'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'URINARY TRACT INFECTION'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered '1000'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Jan 2021 16:40:42



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered '12 Dec 2020'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	28 Jan 2021 17:16:53
User entered '0'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	28 Jan 2021 17:16:53
User entered '12 Dec 2020'	(b) (4), (b) (6)	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 16:40:42



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User entered empty.	System	28 Jan 2021 16:40:42

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User entered empty.	System	28 Jan 2021 16:40:42

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:24
User entered empty.	System	28 Jan 2021 16:40:42

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:16:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 16:46:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 16:46:20
Data point term sent to Coder	System	28 Jan 2021 16:45:51
User entered 'LACTATED RINGERS'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'SYNCOPE'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered '1000'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User closed query ' Per DM CLR Requery: Please review the unit 'ug' as this does not correspond to the given dose of this medication.Kindly confirm if dose unit 'ml' is correct unit else please clarify. Review and update as applicable.' (Site from DM).		09 Mar 2021 06:07:34
Query ' Per DM CLR Requery: Please review the unit 'ug' as this does not correspond to the given dose of this medication.Kindly confirm if dose unit 'ml' is correct unit else please clarify. Review and update as applicable.' answered with 'updated' (Site from DM).		08 Mar 2021 21:09:27
User entered 'mL (mL)' reason for change: Data Entry Error		08 Mar 2021 21:09:18
User opened query ' Per DM CLR Requery: Please review the unit 'ug' as this does not correspond to the given dose of this medication.Kindly confirm if dose unit 'ml' is correct unit else please clarify. Review and update as applicable.' (Site from DM).		01 Mar 2021 04:41:06
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).		01 Mar 2021 04:37:49
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated' (Site from DM).		26 Feb 2021 16:16:03
DataPoint Un-verified.		26 Feb 2021 16:15:56
User entered 'ug (ug)' reason for change: Data Entry Error		26 Feb 2021 16:15:56
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).		18 Feb 2021 16:07:09
DataPoint Verified.		28 Jan 2021 17:16:53
User entered 'mg (mg)'		28 Jan 2021 16:45:50

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2319 of 2689



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	28 Jan 2021 17:16:53
User entered '12 Dec 2020'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 17:16:53
User entered '0'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	28 Jan 2021 17:16:53
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 16:45:50



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	28 Jan 2021 17:16:53
User entered '12 Dec 2020'	(b) (4), (b) (6)	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User closed query 'Data hasn't entered in source. please enter the data.' (Site from CRA).		05 Feb 2021 17:07:16
Query 'Data hasn't entered in source. please enter the data.' answered with 'source data entered ' (Site from CRA).		02 Feb 2021 01:07:27
User opened query 'Data hasn't entered in source. please enter the data.' (Site from CRA).		28 Jan 2021 17:17:54
DataPoint Un-verified.		28 Jan 2021 17:17:39
DataPoint Verified.		28 Jan 2021 17:16:53
User entered 'No (N)'		28 Jan 2021 16:45:50

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User entered empty.	System	28 Jan 2021 16:45:50

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User entered empty.	System	28 Jan 2021 16:45:50

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:15
User entered empty.	System	28 Jan 2021 16:45:50

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TIROFIBAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:19:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:19:50
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
Data point term sent to Coder		10 Mar 2021 03:02:16
Coding entries removed.		10 Mar 2021 03:01:28
Coding entries removed.		10 Mar 2021 03:01:28
User entered 'TIROFIBAN' reason for change: Data Entry Error		10 Mar 2021 03:01:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 02:57:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 02:57:44
Data point term sent to Coder	System	10 Mar 2021 02:57:15
User entered 'LOSARTAN'	(b) (4), (b) (6)	10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Yes (Y)' reason for change: Data Entry Error		10 Mar 2021 03:01:28
User entered 'No (N)'		10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'BLOOD CLOT PROPHYLAXIS'		10 Mar 2021 03:01:28
reason for change: Data Entry Error		
User entered 'HYPERTENSION'		10 Mar 2021 02:56:38



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'UNK' reason for change: Data Entry Error		10 Mar 2021 03:01:28
User entered '50'		10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Other (OTHER)' reason for change:		10 Mar 2021 03:01:28
Data Entry Error		
User entered 'mg (mg)'		10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'UNK' reason for change: Data Entry Error		10 Mar 2021 03:01:28
User entered empty.		10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error		10 Mar 2021 03:01:28
User entered 'once daily (QD)'		10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Intravenous (INTRAVENOUS)'		10 Mar 2021 03:01:28
reason for change: Data Entry Error		
User entered 'Oral (ORAL)'		10 Mar 2021 02:56:38

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '26 Feb 2021' reason for change: Data Entry Error		10 Mar 2021 03:01:28
User entered '12 Dec 2020'		10 Mar 2021 02:56:38



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	10 Mar 2021 03:01:57
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:01:57
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	10 Mar 2021 03:01:28
User entered '26 Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:01:28
User entered '26 Dec 2020'	(b) (4), (b) (6)	10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 02:56:38

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User entered empty.	System	10 Mar 2021 03:01:28
User entered '1'	System	10 Mar 2021 02:56:38

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User entered empty.	System	10 Mar 2021 03:01:28
User entered '1'	System	10 Mar 2021 02:56:38

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:24
User entered empty.	System	10 Mar 2021 03:01:28
User entered '804 (804)'	System	10 Mar 2021 02:56:38

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 08:08:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:08:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:53:53
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
Data point term sent to Coder	System	10 Mar 2021 03:05:17
User entered 'HEPARIN'	(b) (4), (b) (6)	10 Mar 2021 03:04:22



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'BLOOD CLOT PROPHYLAXIS'	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User closed query 'Per source, it is 250 ML 2X, please verify.' (Site from CRA).	(b) (4)	
Query 'Per source, it is 250 ML 2X, please verify.'	(b) (4), (b) (6)	30 Mar 2021 19:29:33
answered with 'SUBJECT WAS IN ICU AND HAD 2 SEPERATE HOSPITALIZATIONS- MEDICATIONS ARE ALL OVER THE PLACE. I REACHED OUT TO MY CRA AND HAD HER LOOK OVER THE 500+ PAGES OF MEDICAL RECORDS AND AM WAITING TO HEAR BACK ON WHICH MEDS MUST BE CAPTURED AND HOW TO BE DO SO. DOSES AND ROUTES CHANGED BY THE DAY, SOME MEDS WERE GIVEN ON A SLIDING SCALE BASED ON LAB RESULTS WHICH WERE DRAWN MULTIPLE TIMES A DAY- PLEASE REQUEST SPONSOR TO SPECIFY HOW THIS CASE SHOULD BE HANDLED' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:20:36
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 23:36:10
DataPoint Verified.		11 Mar 2021 23:34:17
User opened query 'Per source, it is 250 ML 2X, please verify.' (Site from CRA).		11 Mar 2021 23:30:45
User entered 'UNK'		10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User closed query 'Per source, it is 4000 units, please verify.' (Site from CRA).	(b) (4)	30 Mar 2021 19:29:41
Query 'Per source, it is 4000 units, please verify.' answered with 'SUBJECT WAS IN ICU AND HAD 2 SEPERATE HOSPITALIZATIONS- MEDICATIONS ARE ALL OVER THE PLACE. I REACHED OUT TO MY CRA AND HAD HER LOOK OVER THE 500+ PAGES OF MEDICAL RECORDS AND AM WAITING TO HEAR BACK ON WHICH MEDS MUST BE CAPTURED AND HOW TO BE DO SO. DOSES AND ROUTES CHANGED BY THE DAY, SOME MEDS WERE GIVEN ON A SLIDING SCALE BASED ON LAB RESULTS WHICH WERE DRAWN MULTIPLE TIMES A DAY- PLEASE REQUEST SPONSOR TO SPECIFY HOW THIS CASE SHOULD BE HANDLED' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:20:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 23:36:13
DataPoint Verified.		11 Mar 2021 23:34:17
User opened query 'Per source, it is 4000 units, please verify.' (Site from CRA).		11 Mar 2021 23:29:35
User entered 'Other (OTHER)'		10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UNK'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Mar 2021 03:04:22



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User closed query 'Per CDM: Please clarify route because it is not typical route. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:02:59
Query 'Per CDM: Please clarify route because it is not typical route. Thank you!' answered with 'SUBJECT WAS IN ICU AND HAD 2 SEPERATE HOSPITALIZATIONS- MEDICATIONS ARE ALL OVER THE PLACE. I REACHED OUT TO MY CRA AND HAD HER LOOK OVER THE 500+ PAGES OF MEDICAL RECORDS AND AM WAITING TO HEAR BACK ON WHICH MEDS MUST BE CAPTURED AND HOW TO BE DO SO. DOSES AND ROUTES CHANGED BY THE DAY, SOME MEDS WERE GIVEN ON A SLIDING SCALE BASED ON LAB RESULTS WHICH WERE DRAWN MULTIPLE TIMES A DAY- PLEASE REQUEST SPONSOR TO SPECIFY HOW THIS CASE SHOULD BE HANDLED' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 18:19:52
User opened query 'Per CDM: Please clarify route because it is not typical route. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:14:04
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'IV SUB Q'	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Un-verified.	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:56:06
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:56:06
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Un-verified.	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:56:06
User entered '5 Mar 2021' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 17:56:06
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:04:22

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User entered empty.	System	10 Mar 2021 03:04:22

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User entered empty.	System	10 Mar 2021 03:04:22



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:59
User entered empty.	System	10 Mar 2021 03:04:22

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 11:44:09
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:44:09
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
Data point term sent to Coder User entered 'NOREPINEPHRINE'	System (b) (4), (b) (6)	10 Mar 2021 03:07:18 10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 03:07:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 03:07:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:07:09
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 03:06:54
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'WORSENING OF CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'UNK'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UNK'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	10 Mar 2021 03:06:54



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '01 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '01 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:06:54



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User entered empty.	System	10 Mar 2021 03:06:54

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User entered empty.	System	10 Mar 2021 03:06:54

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:06
User entered empty.	System	10 Mar 2021 03:06:54

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: PROTAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 09:57:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 09:57:50
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
Data point term sent to Coder	System	10 Mar 2021 03:11:18
User entered 'PROTAMINE'	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'HEMORRHAGE PROPHYLAXIS'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UNK'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Mar 2021 03:10:44



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'UNK'	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '01 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:10:44



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '01 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:10:44

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User entered empty.	System	10 Mar 2021 03:10:44

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User entered empty.	System	10 Mar 2021 03:10:44

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:33
User entered empty.	System	10 Mar 2021 03:10:44

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:01:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:01:50
	(b) (4)	
Data point term sent to Coder	System	10 Mar 2021 03:15:19
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'WORSENING OF CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	10 Mar 2021 03:14:25



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '20'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	11 Mar 2021 23:34:17
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 03:14:25



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 03:14:25

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Mar 2021 03:14:25

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:20:57
User signature succeeded.	James Peterson (b) (4) (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
Data point term sent to Coder	System	10 Mar 2021 03:19:21
User entered 'SODIUM CHLORIDE 0.45%'	(b) (4), (b) (6)	10 Mar 2021 03:19:00



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:02:24
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 18:44:28
' answered with 'corrected' (Site from DM).		
DataPoint Un-verified.	Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 18:44:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 18:44:18
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	21 Mar 2021 02:28:22
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'SURGICAL PROPHYLAXIS'	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '500'	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'mL (mL)'	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	10 Mar 2021 03:19:00



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:19:00

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User entered empty.	System	10 Mar 2021 03:19:00

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User entered empty.	System	10 Mar 2021 03:19:00



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:43
User entered empty.	System	10 Mar 2021 03:19:00

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:26:42
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
Data point term sent to Coder User entered 'LOSARTAN'	System (b) (4), (b) (6)	10 Mar 2021 03:20:21 10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'WORSENING OF CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '100'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:20:20

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:20:20



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
		10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Un-verified.	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 18:45:39
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 18:45:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Un-verified.	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 18:45:39
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Ashley Bragg (b) (4)	30 Mar 2021 18:45:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:20:20



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User entered '1'	System	10 Mar 2021 03:20:20

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User entered '1'	System	10 Mar 2021 03:20:20

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:28:51
User entered '804 (804)'	System	10 Mar 2021 03:20:20

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL XL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 07:18:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:18:41
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:34:17
Data point term sent to Coder	System	10 Mar 2021 03:22:22
User entered 'TOPROL-XL'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'WORSENING OF CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '25'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Mar 2021 03:21:52



US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	11 Mar 2021 23:34:17
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 03:21:52



US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:09:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 03:22:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 03:22:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 03:22:20
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 03:21:52
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 03:21:52

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 03:21:52

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 03:21:52

US3332033

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:09:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Mar 2021 03:21:52

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:09:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:23
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:14:11
Signature has been broken.		10 Mar 2021 02:50:46
User entered 'Yes (Y)' reason for change: Data Entry Error		10 Mar 2021 02:50:46
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'No (N)'	(b) (4) Kenadie Hamblin (b) (4)	05 Feb 2021 01:08:10
	(b) (4)	

US3332033

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:09:26**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 02:51:39

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'cardiac stent placement'	(b) (4), (b) (6)	10 Mar 2021 02:51:39



US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Mar 2021 02:51:39

US3332033

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:09:26**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 02:51:39

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered '01 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 02:52:08

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'coronary artery bypass graft x 2'	(b) (4), (b) (6)	10 Mar 2021 02:52:08

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Mar 2021 02:52:08

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:46
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 02:52:08

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:47
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 02:52:50

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:47
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'chest x ray'	(b) (4), (b) (6)	10 Mar 2021 02:52:50



US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:47
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Mar 2021 02:52:50

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:47
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 02:52:50

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 02:53:20

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'echocardiogram'	(b) (4), (b) (6)	10 Mar 2021 02:53:20

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Mar 2021 02:53:20

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 02:53:20

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:09:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered '26 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 02:53:57

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:09:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'EKG'	(b) (4), (b) (6)	10 Mar 2021 02:53:57



US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:09:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Mar 2021 02:53:57

US3332033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:09:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:51
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 23:40:28
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 02:53:57

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:02
User entered		
'USA-US202-2021-MRNA-1273-P301000004'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'James'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Peterson'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'US'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
User entered '4'	System	04 Feb 2021 17:37:43
User entered '3'	System	28 Jan 2021 14:00:22
User entered '2'	System	27 Jan 2021 14:48:13
User entered '1'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:02
User entered		
'USA-US202-2021-MRNA-1273-P301000004'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'James'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Peterson'	System	26 Jan 2021 18:18:45



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'US'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
User entered '4'	System	04 Feb 2021 17:37:43
User entered '3'	System	28 Jan 2021 14:00:22
User entered '2'	System	27 Jan 2021 14:48:13
User entered '1'	System	26 Jan 2021 18:19:14

**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:09:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:10:19
User entered '26/Jan/2021 18:19'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:02
User entered		
'USA-US202-2021-MRNA-1273-P301000004'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'James'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Peterson'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'US'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
User entered '4'	System	04 Feb 2021 17:37:43
User entered '3'	System	28 Jan 2021 14:00:22
User entered '2'	System	27 Jan 2021 14:48:13
User entered '1'	System	26 Jan 2021 18:19:14



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:10:19
User entered '27/Jan/2021 14:48'	System	27 Jan 2021 14:48:13

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	28 Jan 2021 14:00:13
DataPoint Verified.		27 Jan 2021 20:10:19
User entered 'I'		27 Jan 2021 14:48:13

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:02
User entered		
'USA-US202-2021-MRNA-1273-P301000004'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'James'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Peterson'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'US'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
User entered '4'	System	04 Feb 2021 17:37:43
User entered '3'	System	28 Jan 2021 14:00:22
User entered '2'	System	27 Jan 2021 14:48:13
User entered '1'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '28/Jan/2021 09:00'	(b) (4) System	28 Jan 2021 14:00:22

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:37:29
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 14:00:22



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:02
User entered		
'USA-US202-2021-MRNA-1273-P301000004'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'No (N)'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'Yes (Y)'	System	27 Jan 2021 14:47:34
Un-reviewed for Safety.	System	27 Jan 2021 01:02:59
User entered 'No (N)'	System	27 Jan 2021 01:02:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Yes (Y)'	System	26 Jan 2021 18:18:45



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'James'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:19:08
User entered 'Peterson'	System	26 Jan 2021 18:18:45

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 20:10:19
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 14:48:02
User entered 'US'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
	(b) (4)	
User entered '4'	System	04 Feb 2021 17:37:43
User entered '3'	System	28 Jan 2021 14:00:22
User entered '2'	System	27 Jan 2021 14:48:13
User entered '1'	System	26 Jan 2021 18:19:14

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:09:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered '04/Feb/2021 12:37'	(b) (4) System	04 Feb 2021 17:37:43

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:37:43

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '01/Mar/2021 13:17'	(b) (4) System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 18:17:23



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '05/Mar/2021 10:37'	(b) (4) System	05 Mar 2021 15:37:11

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 15:37:11

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:26**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23

**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:09:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '09/Mar/2021 09:54'	(b) (4) System	09 Mar 2021 15:54:46

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:10:36
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 15:54:46

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23



**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:09:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '12/Mar/2021 10:10'	(b) (4) System	12 Mar 2021 15:10:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:01:12
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 15:10:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:09:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23

**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:09:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '22/Mar/2021 12:01'	(b) (4) System	22 Mar 2021 17:01:57

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:43:40
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 17:01:57



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:09:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '24/Mar/2021 10:43'	(b) (4) System	24 Mar 2021 10:43:56

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 17:48:21
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 10:43:56

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:09:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '30/Mar/2021 12:48'	(b) (4) System	30 Mar 2021 17:48:36

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:48:09
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:48:36

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:03
User entered 'USA-US202-2021-MRNA-1273-P301000005'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:54:28
Un-reviewed for Safety.	System	05 Mar 2021 15:36:30
User entered 'Yes (Y)'	System	05 Mar 2021 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51



US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Yes (Y)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'No (N)'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'James'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 18:17:07
User entered 'Peterson'	System	01 Mar 2021 18:16:51

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:54:28
User entered 'US'	System	01 Mar 2021 18:17:23

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	12 Apr 2021 13:48:29
User entered '7'	System	30 Mar 2021 17:48:36
User entered '6'	System	24 Mar 2021 10:43:56
User entered '5'	System	22 Mar 2021 17:01:57
User entered '4'	System	12 Mar 2021 15:10:51
User entered '3'	System	09 Mar 2021 15:54:46
User entered '2'	System	05 Mar 2021 15:37:11
User entered '1'	System	01 Mar 2021 18:17:23



**US3332033**

**Folder: SAE USA-US202-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 17:09:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered '12/Apr/2021 08:48'	(b) (4) System	12 Apr 2021 13:48:29

US3332033

Folder: SAE USA-US202-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:09:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:48:29