

US3182227 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:36:16

All time stamps listed in this document are displayed in GMT

US3182227

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:40:28

Generated On: 09 Jun 2021 15:36:16

[Participant ID](#)

US3182227

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

US3182227

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Date of Informed Consent (<i>dd MMM yyyy</i>)	7 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

US3182227

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3182227

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182227

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	HEART ATTACK
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3182227

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

US3182227

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182227

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1983
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1983
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	JAN 1983
Stop Year (derived)	1983

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	SENILE PUPURA BILATERAL ARMS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182227

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3182227

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:31
Height (xxx.x)	156.4 cm
Weight (xxx.x)	62.2 kg
BMI (xxx.x)	25.42827 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182227

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Date of assessment (dd MMM yyyy) 07 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:44:54

Generated On: 09 Jun 2021 15:36:16

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:44:54

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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

Visit date (dd MMM yyyy)	07 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3182227

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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

What was the participant's randomization number? 185201

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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)	07 AUG 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:31
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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)	07 AUG 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:43
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3182227

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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) 7 AUG 2020

What was the treatment time? (00:00-23:59) 12:07 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 12:07

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	07 AUG 2020
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Collection time (00:00-23:59)	11:46 (24 HR)
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Collection date and time (derived)	07 AUG 2020 11:46
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US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:44	07 AUG 2020 11:44
Nasopharyngeal Swab 2	No		

US3182227

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:41

PC Open Date & Time

07 AUG 2020 12:27

PC Close Date & Time

07 AUG 2020 14:57

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	07 AUG 2020 18:16
PC Open Date & Time	07 AUG 2020 15:52
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

98.7 °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

08 AUG 2020 18:32

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 14:19

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 18:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

11 AUG 2020 20:34

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

98.7 °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

12 AUG 2020 18:43

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

13 AUG 2020 18:40

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 12:42

PC Open Date & Time

07 AUG 2020 12:27

PC Close Date & Time

07 AUG 2020 14:57

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:16

PC Open Date & Time

07 AUG 2020 15:52

PC Close Date & Time

08 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

08 AUG 2020 18:33

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

09 AUG 2020 14:19

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

10 AUG 2020 18:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

11 AUG 2020 20:34

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

12 AUG 2020 18:43

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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

13 AUG 2020 18:40

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 ☐

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 12:42
PC Open Date & Time	07 AUG 2020 12:27
PC Close Date & Time	07 AUG 2020 14:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 ☐

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 18:17
PC Open Date & Time	07 AUG 2020 15:52
PC Close Date & Time	08 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

51 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:33
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

53 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 14:20
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

55 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:08
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

57 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 20:34
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

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 ☒

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 18:43
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:40
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3182227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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)	08 SEP 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 08:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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)	08 SEP 2020
Time of assessment (00:00-23:59)	10:07 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3182227

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 09:32 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 09:32

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

US3182227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

09:06 (24 HR)

Collection date and time (derived)

08 SEP 2020 09:06

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:00	08 SEP 2020 09:00
Nasopharyngeal Swab 2	No		

US3182227

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

98.3 °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

08 SEP 2020 10:03

PC Open Date & Time

08 SEP 2020 09:52

PC Close Date & Time

08 SEP 2020 12:22

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	08 SEP 2020 17:00
PC Open Date & Time	08 SEP 2020 13:17
PC Close Date & Time	09 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:43

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 18:53

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

98.1 °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 16:29

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

12 SEP 2020 18:11

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

13 SEP 2020 16:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 16:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

08 SEP 2020 10:04

PC Open Date & Time

08 SEP 2020 09:52

PC Close Date & Time

08 SEP 2020 12:22

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

08 SEP 2020 17:00

PC Open Date & Time

08 SEP 2020 13:17

PC Close Date & Time

09 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

09 SEP 2020 18:43

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

10 SEP 2020 18:53

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

11 SEP 2020 16:29

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

12 SEP 2020 18:11

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

13 SEP 2020 16:34

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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

14 SEP 2020 16:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 ☐

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 10:04
PC Open Date & Time	08 SEP 2020 09:52
PC Close Date & Time	08 SEP 2020 12:22

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 ☐

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:00
PC Open Date & Time	08 SEP 2020 13:17
PC Close Date & Time	09 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

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 ☒

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:44
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

99 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:54
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

101 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

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 ☒

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

105 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:34
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

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

107 of 2113

EAB) (1725)

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 16:11
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3182227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:23:59

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:19:00

Generated On: 09 Jun 2021 15:36:16

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3182227

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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"/>

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 DEC 2020 13:52:43
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 16:36:19

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 07:53:12

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

25 JAN 2021 06:41:16

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 07:42:23

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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	14 FEB 2021 18:09:19
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3182227

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:36:16

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

US3182227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 13:19:50

Generated On: 09 Jun 2021 15:36:16

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

NOT DONE DUE TO SITE ERROR

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 13:19:49

Generated On: 09 Jun 2021 15:36:16

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

NOT DONE DUE TO SITE ERROR

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 13:19:49

Generated On: 09 Jun 2021 15:36:16

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

NOT DONE DUE TO SITE ERROR

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 13:19:49

Generated On: 09 Jun 2021 15:36:16

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

NOT DONE DUE TO SITE ERROR

If Contact Not Made, please provide Comments

US3182227

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 14:55:55

Generated On: 09 Jun 2021 15:36:16

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3182227

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:36:16

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"/>

US3182227

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:36:16

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3182227

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

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

Visit date (dd MMM yyyy)	20 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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US3182227

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Date of updated informed consent (<i>dd MMM yyyy</i>)	20 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	20 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3182227

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	20 JAN 2021
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Collection time (00:00-23:59)	15:10 (24 HR)
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Collection date and time (derived)	20 JAN 2021 15:10
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US3182227

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	20 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	15:02
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Collection Date and Time (derived)	20 JAN 2021 15:02
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US3182227

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:40:28

Generated On: 09 Jun 2021 15:36:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

AEID

Adverse event

LEFT ROTATOR CUFF TEAR

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)

25 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 OCT 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

169 of 2113

EAB) (1725)

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

AEID

Adverse event

BRADYCARDIA

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)

06 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 OCT 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

171 of 2113

EAB) (1725)

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ARTHROPLASTY. FOLLOWING SURGERY HER HEART RATE DROPPED TO 30 AND SHE WAS TAKEN BY AMBULANCE TO ER. SHE WAS LATER ADMITTED DUE TO CARDIAC HISTORY FOR FULL WORK UP AND EVALUATION. SHE WAS DISCHARGED HOME ON 10/9/20. MEDICAL RECORDS PENDING.

MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT HAD ROTATOR CUFF REPAIR SURGERY. IN POST OP- SUBJECT DEVELOPED BRADYCARDIA AND WAS TRANSFERRED TO THE HOSPITAL. UPON ADMISSION, THE SUBJECT UNDERWENT EKG, CHEST CT WITH CONTRAST, A CARDIAC CATHETERIZATION, AND A CHEST X-RAY. SUBJECT WAS DISCHARGED WITH INSTRUCTION TO FOLLOW UP.

CARDIAC CATHETERIZATION- NO STENOSIS
EKG- NORMAL, SINUS RHYTHM WITH SINUS ARRHYTHMIA INCOMPLETE RBBB (NONSPECIFIC EKG CHANGES)
TROPONINS ARE NEGATIVE
CT CHEST NEGATIVE FOR PE.
AFTER INVESTIGATOR REVIEW, IT WAS DEEMED THIS IS NOT A SAE.

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)	0

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

AEID	
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)	24 OCT 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)	24 OCT 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

SUBJECT REPORTED NOT
FEELING WELL ON 10/27/20, SHE
HAD SYNCOPAL EPISODE AT
HOME WITH HUSBAND
PRESENT. HE CALLED 911 AND
SHE WAS TAKEN BY
AMBULANCE TO HOSPITAL
WHERE SHE WAS ADMITTED
FOR EVALUATION. SHE WAS
DISCHARGED HOME ON
10/26/20. MEDICAL RECORDS
PENDING.

MEDICAL RECORDS RECEIVED
AND REVIEWED. SUBJECT
PRESENTED TO ED FOR
CONCERNS OF
DEHYDRATIONS,
DIZZINESS/LIGHTHEADEDNESS
, DIARRHEA AND
GENERALIZED WEAKNESS.
SUBJECT STOPPED HER
NARCOTIC PAIN MEDICATION
AT HOME DUE TO
CONSTIPATION. TOOK A
LAXATIVE AND STARTED
HAVING DIARRHEA. AN EKG
WAS DONE IN THE ED, SHOWED
TACHYCARDIA (149BPM). CT OF
CHEST WAS NEGATIVE FOR PE.
CT OF BRAIN SHOWED NO
ACUTE INTRACRANIAL
PROCESS. FOUND TO BE
ORTHOSTATIC, GIVEN IV
FLUIDS. ADMITTED FOR

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

FURTHER EVALUATION.

SUBJECT HAD A COVID
NASOPHARYNGEAL SWAB ON
10/24/2020 WHICH RESULTED IN
A NEGATIVE RESULT.

AFTER REVIEW WITH
INVESTIGATOR, IT WAS
DEEMED THIS WAS NOT A SAE.

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)	0

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

AEID

Adverse event

INFRAHILAR ATELECTASIS

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)

06 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 12:19:06

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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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

AEID	USA-US075-2020-MRNA-1273-P30 1000004
Adverse event	DEHYDRATION
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)	24 OCT 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)	26 OCT 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	True
Hospital Admission Date (dd MMM yyyy)	24 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	26 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 12:19:06

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

SUBJECT REPORTED NOT
FEELING WELL ON 10/24/20, SHE
HAD SYNCOPAL EPISODE AT
HOME WITH HUSBAND
PRESENT. HE CALLED 911 AND
SHE WAS TAKEN BY
AMBULANCE TO HOSPITAL
WHERE SHE WAS ADMITTED
FOR EVALUATION. SHE WAS
DISCHARGED HOME ON
10/26/20. MEDICAL RECORDS
PENDING.

MEDICAL RECORDS RECEIVED
AND REVIEWED. SUBJECT
PRESENTED TO ED FOR
CONCERNS OF
DEHYDRATIONS,
DIZZINESS/LIGHTHEADEDNESS
, DIARRHEA AND
GENERALIZED WEAKNESS.
SUBJECT STOPPED HER
NARCOTIC PAIN MEDICATION
AT HOME DUE TO
CONSTIPATION. TOOK A
LAXATIVE AND STARTED
HAVING DIARRHEA. AN EKG
WAS DONE IN THE ED, SHOWED
TACHYCARDIA (149BPM). CT OF
CHEST WAS NEGATIVE FOR PE.
CT OF BRAIN SHOWED NO
ACUTE INTRACRANIAL
PROCESS. FOUND TO BE
ORTHOSTATIC, GIVEN IV
FLUIDS. ADMITTED FOR

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

FURTHER EVALUATION.

SUBJECT HAD A COVID
NASOPHARYNGEAL SWAB ON
10/24/2020 WHICH RESULTED IN
A NEGATIVE RESULT.

ALTHOUGH THE DISCHARGE
SUMMARY SAYS
GENERALIZED WEAKNESS,
AFTER INVESTIGATOR'S
REVIEW OF RECORDS, IT IS
INDICATED THAT THE
WEAKNESS WAS DUE TO THE
DEHYDRATION TREATED WITH
IV FLUIDS.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

AEID

Adverse event

GENERALIZED WEAKNESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 OCT 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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 12:19:06

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

AEID	USA-US075-2020-MRNA-1273-P30 1000004
Adverse event	CHEST PAIN (NON-CARDIAC)
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)	06 OCT 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)	09 OCT 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	True
Hospital Admission Date (dd MMM yyyy)	06 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	09 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 12:19:06

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ARTHROPLASTY. FOLLOWING SURGERY HER HEART RATE DROPPED TO 30 AND SHE WAS TAKEN BY AMBULANCE TO ER. SHE WAS LATER ADMITTED DUE TO CARDIAC HISTORY FOR FULL WORK UP AND EVALUATION. SHE WAS DISCHARGED HOME ON 10/9/20. MEDICAL RECORDS PENDING.

MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT HAD ROTATOR CUFF REPAIR SURGERY. IN POST OP- SUBJECT DEVELOPED BRADYCARDIA AND REPORTED CHEST PAIN, SHE WAS TRANSFERRED TO THE HOSPITAL. UPON ADMISSION, THE SUBJECT UNDERWENT EKG, CHEST CT WITH CONTRAST, A CARDIAC CATHETERIZATION AND A CHEST X-RAY. SUBJECT WAS DISCHARGED WITH INSTRUCTION TO FOLLOW UP.

CARDIAC CATHETERIZATION- NO STENOSIS
EKG- NORMAL, SINUS RHYTHM WITH SINUS ARRHYTHMIA INCOMPLETE RBBB (NONSPECIFIC EKG CHANGES)
TROPONINS ARE NEGATIVE
CT CHEST NEGATIVE FOR PE.

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

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 12:19:06

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 12:19:06

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	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 1998
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

	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 1998
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN, NON CARDIAC.

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

	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)		6 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 OCT 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"/>

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Name of Medication IV FLUIDS

Prophylaxis Yes ☐
No ☒

Indication DEHYDRATION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 OCT 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"/>

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY TO LEFT
ARTHROPLASTY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN.

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 12:19:06

Generated On: 09 Jun 2021 15:36:16

	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)	UN OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 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"/>

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:40:29

Generated On: 09 Jun 2021 15:36:16

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 13:19:49

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 OCT 2020	EKG	Diagnostic	
24 OCT 2020	EKG	Diagnostic	
7 OCT 2020	CARDIAC CATHETERIZATION	Adverse Event	
6 OCT 2020	CHEST CT WITH CONTRAST	Diagnostic	
8 OCT 2020	CHEST X-RAY	Diagnostic	
24 OCT 2020	CHEST X-RAY	Diagnostic	
24 OCT 2020	CT OF BRAIN	Diagnostic	
24 OCT 2020	CHEST CT WITH CONTRAST	Diagnostic	
06 OCT 2020	LEFT SHOULDER ARTHROPLASTY	Adverse Event	
6 OCT 2020	BLOODWORK (TROPONIN)	Diagnostic	

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 27 Mar 2021 16:57:01

Generated On: 09 Jun 2021 15:36:16

Date of study discontinuation/completion (dd MMM yyyy) 02 MAR 2021

Reason for discontinuation

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

SUBJECT CHOICE TO WITHDRAWAL

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

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

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/OCT/2020 13:06
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

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/NOV/2020 20:25
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

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	01/MAR/2021 11:49
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

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/MAR/2021 12:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	31/MAR/2021 11:10
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

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	14/APR/2021 12:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Apr 2021 15:17:46

Generated On: 09 Jun 2021 15:36:16

SAEID	USA-US075-2020-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 checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/APR/2021 06:06
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

US3182227 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182227

Form: Participant Creation

Generated On: 09 Jun 2021 15:36:16

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:28:47
User entered 'US3182227'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:39:50

US3182227

Form: Participant Creation

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:33:36
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:07

US3182227

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:33:36
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:39:51

US3182227

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:33:36
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:07

US3182227

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'SCRN'	System	13 Aug 2020 18:10:07

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:39:52

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '69'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'YEARS'	System	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '69'	System	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered 'Female (F)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:36:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:10:25

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:31
User entered '7 Aug 2020'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Aug 2020'	System	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '2020'	System	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:31
User entered 'Amendment 1 (1)'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:31
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:31
User entered empty.	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:31
User entered empty.	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:31
User entered 'No (N)'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:13:31

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:34:31
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:39:51

US3182227

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:36:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'I'	System	07 Aug 2020 16:13:37

US3182227

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:35:36
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:13:37

US3182227

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:36:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:35:42
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:06

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:30:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:30:23
Data point term sent to Coder	System	13 Aug 2020 18:29:39
User entered 'Presbyopia'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 2005'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 2005'	System	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '2005'	System	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:29:18

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:30:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:30:23
Data point term sent to Coder	System	13 Aug 2020 18:29:39
User entered 'Heart Attack'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 1998'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:01
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of HEART ATTACK may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 05:12:38
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of HEART ATTACK may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 18:53:01
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 18:52:57
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 18:52:57
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of HEART ATTACK may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:17:18
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:04
DataPoint Un-verified.	Cassie Uminski (b) (4)	10 Sep 2020 18:52:57
User entered 'un UNK 1998' reason for change:	(b) (4)	10 Sep 2020 18:52:57
Data Entry Error	Cassie Uminski (b) (4)	10 Sep 2020 18:52:57
DataPoint Verified.	(b) (4)	20 Aug 2020 13:32:46
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 1998'	System	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '1998'	System	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 1998'	System	10 Sep 2020 18:52:57
User entered empty.	System	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '1998'	System	10 Sep 2020 18:52:57
User entered empty.	System	13 Aug 2020 18:29:30

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
Data point term sent to Coder	System	13 Aug 2020 18:30:41
User entered 'Coronary artery disease'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:48

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 1998'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:48

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 1998'	System	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '1998'	System	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:29:48

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
Data point term sent to Coder	System	13 Aug 2020 18:30:42
User entered 'High Cholesterol'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 2010'	System	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '2010'	System	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:30:04

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
Data point term sent to Coder	System	13 Aug 2020 18:30:41
User entered 'Hypertension'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 1998'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 1998'	System	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '1998'	System	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:30:17

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:31:22
Data point term sent to Coder	System	13 Aug 2020 18:30:43
User entered 'Hypothyroidism'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 2013'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 2013'	System	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '2013'	System	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:30:32

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
User closed query 'Per DM CLR : Please review the response in 'If No, what is the reason?' field in Childbearing Potential eCRF as it does not match with this corresponding medical procedure. Please reconcile and update data as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:16:03
Query 'Per DM CLR : Please review the response in 'If No, what is the reason?' field in Childbearing Potential eCRF as it does not match with this corresponding medical procedure. Please reconcile and update data as appropriate.' answered with 'Please advise as the subject is also menopausal. ' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 18:54:26
User opened query 'Per DM CLR : Please review the response in 'If No, what is the reason?' field in Childbearing Potential eCRF as it does not match with this corresponding medical procedure. Please reconcile and update data as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:18:27
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:32:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:32:23
Data point term sent to Coder	System	13 Aug 2020 18:31:43
User entered 'Tubal Ligation'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 1983'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 1983'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 1983'	System	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '1983'	System	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 1983'	System	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '1983'	System	13 Aug 2020 18:30:50

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin vascular abnormalities, HLT: Purpura and related conditions, PT: Purpura senile, LLT: Purpura senile - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 13:57:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 13:57:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:25:22
Data point term sent to Coder	System	29 Oct 2020 16:04:22
Coding entries removed.	Cassie Uminski (b) (4)	29 Oct 2020 16:04:06
User entered 'Senile pupura BILATERAL ARMS' reason for change: Data Entry Error	Cassie Uminski (b) (4)	29 Oct 2020 16:04:06
User closed query 'Per DM CLR: Please specify the location of ECCHYMOSIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:39:30
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin vascular abnormalities, HLT: Purpura and related conditions, PT: Ecchymosis, LLT: Ecchymosis - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 08:14:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 08:14:40
Data point term sent to Coder	System	17 Sep 2020 18:25:35
Query 'Per DM CLR: Please specify the location of ECCHYMOSIS. Review and update Med History eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4)	17 Sep 2020 18:25:13
DataPoint Un-verified.	Cassie Uminski (b) (4)	17 Sep 2020 18:25:09
Coding entries removed.	Cassie Uminski (b) (4)	17 Sep 2020 18:25:09
User entered 'ECCHYMOSIS bilateral arms' reason for change: Data Entry Error	Cassie Uminski (b) (4)	17 Sep 2020 18:25:09
User opened query 'Per DM CLR: Please specify the location of ECCHYMOSIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:18:44

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EAB) (1725)

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:32:46
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin vascular abnormalities, HLT: Purpura and related conditions, PT: Ecchymosis, LLT: Ecchymosis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 17:50:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 17:50:37
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 17:49:03
User entered 'Ecchymosis'	Cassie Uminski (b) (4)	19 Aug 2020 17:48:05
	(b) (4)	

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 17:20:38
(Site from DM).		
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:05:31
answered with 'Per investigator, updated term to best describe this chronic condition.'		
(Site from DM).		
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.'	(b) (4), (b) (6)	15 Oct 2020 06:18:51
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:32:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 2010'	System	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '2010'	System	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	19 Aug 2020 17:48:05

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:50
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:27:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:27:45
Data point term sent to Coder	System	17 Sep 2020 18:26:39
User entered 'Menopause'	Cassie Uminski (b) (4) (b) (4)	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:50
User entered 'un UNK 2005'	Cassie Uminski (b) (4) (b) (4)	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:50
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:50
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:50
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:50
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'Jan 2005'	System	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '2005'	System	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	17 Sep 2020 18:26:11

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered '11:31'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '07 Aug 2020 11:31'	System	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered '156.4' cm	Cassie Uminski (b) (4)	13 Aug 2020 18:19:23
DataPoint set to visible.	(b) (4) System	07 Aug 2020 16:13:37

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered '62.2' kg	Cassie Uminski (b) (4)	13 Aug 2020 18:19:23
DataPoint set to visible.	(b) (4) System	07 Aug 2020 16:13:37

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
Amendment Manager: User entered '25.42827'	System	16 Sep 2020 23:47:18
User entered '25.4'	System	13 Aug 2020 18:19:23
DataPoint set to visible.	System	07 Aug 2020 16:13:37

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'kg/m2'	System	13 Aug 2020 18:19:23
DataPoint set to visible.	System	07 Aug 2020 16:13:37

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 12:11:44
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 05:11:17
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 18:51:35
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 18:51:30
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 18:51:30
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 05:43:01
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'bpm'	System	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'breaths/min'	System	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:36:03
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	13 Aug 2020 18:19:23

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15

US3182227

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:36:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15

US3182227

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:03
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:04

US3182227

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
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 15:45:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 13:39:50
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:37:03
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:04

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered 'un UNK 2005'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:36:16

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:37:41
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:24:59

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
User entered 'I'	Cassie Uminski (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
User entered '0'	Cassie Uminski (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:36:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:13
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:58

US3182227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:18

US3182227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:28
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:18

US3182227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:28
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:18

US3182227

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'VISIT1'	System	13 Aug 2020 18:28:18

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:55
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 16:04:35

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:51:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:51:18
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:38:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 16:04:35
User entered '185201' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 16:04:35

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:55
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 16:04:35

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:55
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:25:28

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:55
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:25:28

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:55
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:25:28

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:55
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:25:28

US3182227

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:36:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:38:55
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:25:28

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '11:31'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '07 Aug 2020 11:31'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '98.1' F	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '67'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'bpm'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '14'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'breaths/min'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '102'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '69'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:36:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 19:13:14
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).		13 Aug 2020 18:22:34
User entered '12:43'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '07 Aug 2020 12:43'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '96.8' F	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '61'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'bpm'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '14'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'breaths/min'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '103'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:40:08
User entered '67'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	13 Aug 2020 18:22:34

US3182227

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:41:44
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:11

US3182227

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:41:44
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:11

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:02
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:02
User entered empty.	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:02
User entered empty.	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:02
User entered '7 Aug 2020'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:02
User entered '12:07'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '7 Aug 2020 12:07'	System	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:02
User entered 'Left Arm (LEFT ARM)'	Brooke Glivar (b) (4) (b) (4)	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
DataPoint Verified.		20 Aug 2020 13:42:02
User entered 'ONCE'	System	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 16:14:07

US3182227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:23
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:05

US3182227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:23
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:05

US3182227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:23
User entered '11:46'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:05

US3182227

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '07 Aug 2020 11:46'	System	13 Aug 2020 18:28:05

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:32
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:32
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:31

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:32
User entered '11:44'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '07 Aug 2020 11:44'	System	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:32
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:32
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	13 Aug 2020 18:27:31

US3182227

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:42:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:28:09

US3182227

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'I'	System	13 Aug 2020 18:28:09

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:41:17', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '163f31dd-58b2-4d9d-8b9a-ae8d1037f852'	System	07 Aug 2020 16:41:38
User entered 'Yes (Y)'	System	07 Aug 2020 16:41:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:41:25', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '163f31dd-58b2-4d9d-8b9a-ae8d1037f852'	System	07 Aug 2020 16:41:38
User entered '96.8'	System	07 Aug 2020 16:41:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:41:29', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '163f31dd-58b2-4d9d-8b9a-ae8d1037f852'	System	07 Aug 2020 16:41:38
User entered 'No (N)'	System	07 Aug 2020 16:41:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:41:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '163f31dd-58b2-4d9d-8b9a-ae8d1037f852' User entered '07 Aug 2020 12:41'	System	07 Aug 2020 16:41:38
	System	07 Aug 2020 16:41:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 12:27'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 14:57'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:01', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '00689071-8db3-4e57-be5e-4160e3265ef9'	System	07 Aug 2020 22:20:48
User entered 'Yes (Y)'	System	07 Aug 2020 22:20:48

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:10', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '00689071-8db3-4e57-be5e-4160e3265ef9' User entered '98.7'	System	07 Aug 2020 22:20:48
	System	07 Aug 2020 22:20:48

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:14', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '00689071-8db3-4e57-be5e-4160e3265ef9'	System	07 Aug 2020 22:20:48
User entered 'No (N)'	System	07 Aug 2020 22:20:48

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:21', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '00689071-8db3-4e57-be5e-4160e3265ef9'	System	07 Aug 2020 22:20:48
User entered '07 Aug 2020 18:16'	System	07 Aug 2020 22:20:48

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 15:52'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 2'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:05', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '68d1948b-2871-4b8a-9a5a-e4ff7494b00e' User entered 'Yes (Y)'	System	12 Aug 2020 00:34:10
	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:36', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '68d1948b-2871-4b8a-9a5a-e4ff7494b00e' User entered '98.7'	System	12 Aug 2020 00:34:10
	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:39', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '68d1948b-2871-4b8a-9a5a-e4ff7494b00e' User entered 'No (N)'	System	12 Aug 2020 00:34:10
	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:46', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '68d1948b-2871-4b8a-9a5a-e4ff7494b00e' User entered '08 Aug 2020 18:32'	System	12 Aug 2020 00:34:10
	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 3'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:16', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '404c2c13-04b8-4185-b9f8-1d4da03bf82d' User entered 'Yes (Y)'	System	12 Aug 2020 00:34:12
	System	12 Aug 2020 00:34:12

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:19', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '404c2c13-04b8-4185-b9f8-1d4da03bf82d' User entered '98.8'	System	12 Aug 2020 00:34:12
	System	12 Aug 2020 00:34:12

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '404c2c13-04b8-4185-b9f8-1d4da03bf82d' User entered 'No (N)'	System	12 Aug 2020 00:34:12
	System	12 Aug 2020 00:34:12

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:27', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '404c2c13-04b8-4185-b9f8-1d4da03bf82d' User entered '09 Aug 2020 14:19'	System	12 Aug 2020 00:34:12
	System	12 Aug 2020 00:34:12

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 4'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:18', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d5f74bc-4fda-4437-8d1d-16a7abe5ee19' User entered 'Yes (Y)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:22', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d5f74bc-4fda-4437-8d1d-16a7abe5ee19' User entered '98.5'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:26', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d5f74bc-4fda-4437-8d1d-16a7abe5ee19' User entered 'No (N)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:31', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d5f74bc-4fda-4437-8d1d-16a7abe5ee19' User entered '10 Aug 2020 18:07'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 5'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:07', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd16f9614-7084-4c3e-b77c-831157362e45' User entered 'Yes (Y)'	System	12 Aug 2020 00:34:22
	System	12 Aug 2020 00:34:22

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd16f9614-7084-4c3e-b77c-831157362e45' User entered '98.5'	System	12 Aug 2020 00:34:22
	System	12 Aug 2020 00:34:22

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:14', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd16f9614-7084-4c3e-b77c-831157362e45'	System	12 Aug 2020 00:34:22
User entered 'No (N)'	System	12 Aug 2020 00:34:22

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:20', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd16f9614-7084-4c3e-b77c-831157362e45' User entered '11 Aug 2020 20:34'	System	12 Aug 2020 00:34:22
	System	12 Aug 2020 00:34:22

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 6'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e26b8331-0790-4fb8-bff5-4cad23d0d908'	System	12 Aug 2020 22:43:26
User entered 'Yes (Y)'	System	12 Aug 2020 22:43:26

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:17', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e26b8331-0790-4fb8-bff5-4cad23d0d908' User entered '98.7'	System	12 Aug 2020 22:43:26
	System	12 Aug 2020 22:43:26

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:19', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e26b8331-0790-4fb8-bff5-4cad23d0d908'	System	12 Aug 2020 22:43:26
User entered 'No (N)'	System	12 Aug 2020 22:43:26

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:22', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e26b8331-0790-4fb8-bff5-4cad23d0d908' User entered '12 Aug 2020 18:43'	System	12 Aug 2020 22:43:26
	System	12 Aug 2020 22:43:26

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 7'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:12', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'b8815d44-13f7-4629-b3be-0c6669fdec80' User entered 'Yes (Y)'	System	14 Aug 2020 23:50:38
	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:16', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'b8815d44-13f7-4629-b3be-0c6669fdec80' User entered '98.6'	System	14 Aug 2020 23:50:38
	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:18', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'b8815d44-13f7-4629-b3be-0c6669fdec80'	System	14 Aug 2020 23:50:38
User entered 'No (N)'	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:22', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'b8815d44-13f7-4629-b3be-0c6669fdec80' User entered '13 Aug 2020 18:40'	System	14 Aug 2020 23:50:38
	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:06', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0a83c772-426a-45ac-a27a-df118bf89740' User entered 'None (1)'	System	07 Aug 2020 16:42:28
	System	07 Aug 2020 16:42:28

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0a83c772-426a-45ac-a27a-df118bf89740' User entered 'No (N)'	System	07 Aug 2020 16:42:28
	System	07 Aug 2020 16:42:28

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:14', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0a83c772-426a-45ac-a27a-df118bf89740' User entered 'No (N)'	System	07 Aug 2020 16:42:28
	System	07 Aug 2020 16:42:28

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0a83c772-426a-45ac-a27a-df118bf89740' User entered 'None (1)'	System	07 Aug 2020 16:42:28
	System	07 Aug 2020 16:42:28

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:26', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0a83c772-426a-45ac-a27a-df118bf89740' User entered '07 Aug 2020 12:42'	System	07 Aug 2020 16:42:28
	System	07 Aug 2020 16:42:28

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 12:27'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 14:57'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:29', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '79dfc987-7353-45ba-9830-6771c79e8036'	System	08 Aug 2020 10:39:35
User entered 'None (1)'	System	08 Aug 2020 10:39:35

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '79dfc987-7353-45ba-9830-6771c79e8036'	System	08 Aug 2020 10:39:35
User entered 'No (N)'	System	08 Aug 2020 10:39:35

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '79dfc987-7353-45ba-9830-6771c79e8036'	System	08 Aug 2020 10:39:35
User entered 'No (N)'	System	08 Aug 2020 10:39:35

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:39', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '79dfc987-7353-45ba-9830-6771c79e8036'	System	08 Aug 2020 10:39:35
User entered 'None (1)'	System	08 Aug 2020 10:39:35

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:47', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '79dfc987-7353-45ba-9830-6771c79e8036' User entered '07 Aug 2020 18:16'	System	08 Aug 2020 10:39:35
	System	08 Aug 2020 10:39:35

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 15:52'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 2'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f6c1e99a-320d-45fe-8d8e-f25b75a398d4'	System	12 Aug 2020 00:34:10
User entered 'None (1)'	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:53', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f6c1e99a-320d-45fe-8d8e-f25b75a398d4'	System	12 Aug 2020 00:34:10
User entered 'No (N)'	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:56', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f6c1e99a-320d-45fe-8d8e-f25b75a398d4'	System	12 Aug 2020 00:34:10
User entered 'No (N)'	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:32:59', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f6c1e99a-320d-45fe-8d8e-f25b75a398d4'	System	12 Aug 2020 00:34:10
User entered 'None (1)'	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:03', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f6c1e99a-320d-45fe-8d8e-f25b75a398d4' User entered '08 Aug 2020 18:33'	System	12 Aug 2020 00:34:10
	System	12 Aug 2020 00:34:10

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 3'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:31', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f14b9d8a-7a4d-44d9-9425-22a7fd8da9a7'	System	12 Aug 2020 00:34:13
User entered 'None (1)'	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:34', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f14b9d8a-7a4d-44d9-9425-22a7fd8da9a7' User entered 'No (N)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:36', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f14b9d8a-7a4d-44d9-9425-22a7fd8da9a7'	System	12 Aug 2020 00:34:13
User entered 'No (N)'	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:39', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f14b9d8a-7a4d-44d9-9425-22a7fd8da9a7'	System	12 Aug 2020 00:34:13
User entered 'None (1)'	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:43', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f14b9d8a-7a4d-44d9-9425-22a7fd8da9a7' User entered '09 Aug 2020 14:19'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 4'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:34', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd6fc7beb-e8b1-4ff3-bc86-46421e041656'	System	12 Aug 2020 00:34:14
User entered 'None (1)'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:37', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd6fc7beb-e8b1-4ff3-bc86-46421e041656'	System	12 Aug 2020 00:34:14
User entered 'No (N)'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:40', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd6fc7beb-e8b1-4ff3-bc86-46421e041656'	System	12 Aug 2020 00:34:14
User entered 'No (N)'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:42', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd6fc7beb-e8b1-4ff3-bc86-46421e041656'	System	12 Aug 2020 00:34:14
User entered 'None (1)'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:45', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd6fc7beb-e8b1-4ff3-bc86-46421e041656'	System	12 Aug 2020 00:34:14
User entered '10 Aug 2020 18:07'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 5'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '17c7ed40-73a6-4f89-a8ed-3a6c15035258'	System	12 Aug 2020 00:34:38
User entered 'None (1)'	System	12 Aug 2020 00:34:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:25', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '17c7ed40-73a6-4f89-a8ed-3a6c15035258' User entered 'No (N)'	System	12 Aug 2020 00:34:38
	System	12 Aug 2020 00:34:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:27', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '17c7ed40-73a6-4f89-a8ed-3a6c15035258' User entered 'No (N)'	System	12 Aug 2020 00:34:38
	System	12 Aug 2020 00:34:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:30', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '17c7ed40-73a6-4f89-a8ed-3a6c15035258' User entered 'None (1)'	System	12 Aug 2020 00:34:38
	System	12 Aug 2020 00:34:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:33', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '17c7ed40-73a6-4f89-a8ed-3a6c15035258' User entered '11 Aug 2020 20:34'	System	12 Aug 2020 00:34:38
	System	12 Aug 2020 00:34:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 6'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:25', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ba726137-46b3-4527-8dda-44529c043268'	System	14 Aug 2020 23:50:37
User entered 'None (1)'	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:28', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ba726137-46b3-4527-8dda-44529c043268' User entered 'No (N)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:30', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ba726137-46b3-4527-8dda-44529c043268' User entered 'No (N)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ba726137-46b3-4527-8dda-44529c043268'	System	14 Aug 2020 23:50:37
User entered 'None (1)'	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:39', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ba726137-46b3-4527-8dda-44529c043268' User entered '12 Aug 2020 18:43'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 7'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:25', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1c4bfed5-d574-41d0-b05b-a02930675e63'	System	14 Aug 2020 23:50:38
User entered 'None (1)'	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:29', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1c4bfed5-d574-41d0-b05b-a02930675e63'	System	14 Aug 2020 23:50:38
User entered 'No (N)'	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:30', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1c4bfed5-d574-41d0-b05b-a02930675e63' User entered 'No (N)'	System	14 Aug 2020 23:50:38
	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1c4bfed5-d574-41d0-b05b-a02930675e63'	System	14 Aug 2020 23:50:38
User entered 'None (1)'	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1c4bfed5-d574-41d0-b05b-a02930675e63' User entered '13 Aug 2020 18:40'	System	14 Aug 2020 23:50:38
	System	14 Aug 2020 23:50:38

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae' User entered 'None (0)'	System	07 Aug 2020 16:42:58
	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:37', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae' User entered 'None (0)'	System	07 Aug 2020 16:42:58
	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:41', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae' User entered 'None (0)'	System	07 Aug 2020 16:42:58
	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:44', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae' User entered 'None (0)'	System	07 Aug 2020 16:42:58
	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:47', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae' User entered 'None (0)'	System	07 Aug 2020 16:42:58
	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:49', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae' User entered 'None (0)'	System	07 Aug 2020 16:42:58
	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae'	System	07 Aug 2020 16:42:58
User entered 'No (N)'	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T12:42:55', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a9ed4b5-3d8f-43fe-9216-fb6809fa19ae' User entered '07 Aug 2020 12:42'	System	07 Aug 2020 16:42:58
	System	07 Aug 2020 16:42:58

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 12:27'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 14:57'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caaec9' User entered 'None (0)'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:57', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caaec9' User entered 'None (0)'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:16:59', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caaec9' User entered 'None (0)'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:17:01', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caaec9' User entered 'None (0)'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:17:03', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caaec9' User entered 'None (0)'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:17:05', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caaec9' User entered 'None (0)'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:17:08', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caec9' User entered 'No (N)'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-07T18:17:13', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a788adb2-863a-469f-adc4-94ab49caaec9' User entered '07 Aug 2020 18:17'	System	08 Aug 2020 10:39:36
	System	08 Aug 2020 10:39:36

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '07 Aug 2020 15:52'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 2'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:07', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered 'None (0)'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:09', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered 'None (0)'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered 'None (0)'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:13', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered 'None (0)'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:15', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered 'None (0)'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:18', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered 'None (0)'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:20', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered 'No (N)'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-08T18:33:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '2f7670ab-db62-45ca-a6d5-583c8daa229e' User entered '08 Aug 2020 18:33'	System	12 Aug 2020 00:34:11
	System	12 Aug 2020 00:34:11

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 3'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:46', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88' User entered 'None (0)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88' User entered 'None (0)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:49', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88' User entered 'None (0)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:51', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88' User entered 'None (0)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:53', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88' User entered 'None (0)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:55', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88' User entered 'None (0)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:19:58', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88' User entered 'No (N)'	System	12 Aug 2020 00:34:13
	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-09T14:20:01', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4d6fbede-7730-42f6-8af4-91c07d6b3c88'	System	12 Aug 2020 00:34:13
User entered '09 Aug 2020 14:20'	System	12 Aug 2020 00:34:13

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 4'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:49', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346' User entered 'None (0)'	System	12 Aug 2020 00:34:14
	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346' User entered 'None (0)'	System	12 Aug 2020 00:34:14
	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346' User entered 'None (0)'	System	12 Aug 2020 00:34:14
	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:54', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346' User entered 'None (0)'	System	12 Aug 2020 00:34:14
	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:56', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346' User entered 'None (0)'	System	12 Aug 2020 00:34:14
	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:07:58', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346'	System	12 Aug 2020 00:34:14
User entered 'None (0)'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:08:03', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346'	System	12 Aug 2020 00:34:14
User entered 'No (N)'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-10T18:08:09', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8295b999-4b76-4918-adca-0257dd289346'	System	12 Aug 2020 00:34:14
User entered '10 Aug 2020 18:08'	System	12 Aug 2020 00:34:14

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 5'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:37', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered 'None (0)'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:39', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered 'None (0)'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:41', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered 'None (0)'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:43', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered 'None (0)'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:45', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered 'None (0)'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered 'None (0)'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered 'No (N)'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-11T20:34:53', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6c1498de-3869-406b-bb28-0bf33e09bb43' User entered '11 Aug 2020 20:34'	System	12 Aug 2020 00:34:57
	System	12 Aug 2020 00:34:57

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 6'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:43', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered 'None (0)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:45', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered 'None (0)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered 'None (0)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered 'None (0)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered 'None (0)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:54', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered 'None (0)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:56', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered 'No (N)'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-12T18:43:59', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'df1ba687-128c-478c-af08-795081c0baf5' User entered '12 Aug 2020 18:43'	System	14 Aug 2020 23:50:37
	System	14 Aug 2020 23:50:37

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 7'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:41', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5'	System	14 Aug 2020 23:50:39
User entered 'None (0)'	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:43', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5' User entered 'None (0)'	System	14 Aug 2020 23:50:39
	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:45', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5' User entered 'None (0)'	System	14 Aug 2020 23:50:39
	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5' User entered 'None (0)'	System	14 Aug 2020 23:50:39
	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5' User entered 'None (0)'	System	14 Aug 2020 23:50:39
	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5'	System	14 Aug 2020 23:50:39
User entered 'None (0)'	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:54', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5' User entered 'No (N)'	System	14 Aug 2020 23:50:39
	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-08-13T18:40:57', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'ff5ddac0-7a28-449a-ba27-eb173ddd28a5' User entered '13 Aug 2020 18:40'	System	14 Aug 2020 23:50:39
	System	14 Aug 2020 23:50:39

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 16:14:07

US3182227

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:01
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 13:51:36

US3182227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:01
User entered '14 Aug 2020'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 13:51:36

US3182227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:01
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 13:51:36

US3182227

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:01
User entered empty.	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 13:51:36

US3182227

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:07
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 13:51:21

US3182227

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User entered 'I'	System	20 Aug 2020 13:51:21

US3182227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:30
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:16:55

US3182227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:30
User entered '21 Aug 2020'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:16:55

US3182227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:30
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:16:55

US3182227

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:30
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:16:55

US3182227

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:34:37
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:16:48

US3182227

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:44:35
User entered 'I'	System	24 Aug 2020 13:16:48

US3182227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:33:52
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:01
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:11:35

US3182227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:33:52
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:01
User entered '28 Aug 2020'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:11:35

US3182227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:33:52
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:01
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:11:35

US3182227

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:33:52
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:01
User entered empty.	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:11:35

US3182227

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:33:52
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:07
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:11:28

US3182227

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:33:52
User entered 'I'	System	31 Aug 2020 13:11:28

US3182227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:55
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:39:50

US3182227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:55
User entered '8 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:39:50

US3182227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:55
User entered 'Clinic (Clinic)'	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:39:50

US3182227

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'VISIT2'	System	08 Sep 2020 13:39:50

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '08 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '08:55'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '08 Sep 2020 08:55'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '97.5' F	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered empty.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '53'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'bpm'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '14'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'breaths/min'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '119'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '73'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '08 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '10:07'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '08 Sep 2020 10:07'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '98.3' F	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered empty.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '53'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'bpm'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '16'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'breaths/min'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '123'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:03
User entered '65'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:36:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'mmHg'	System	10 Sep 2020 19:01:09

US3182227

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
User closed query 'Bruising is noted on the PE, should this be captured as an AE?' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:27:28
Query 'Bruising is noted on the PE, should this be captured as an AE?' answered with 'This refers to the senile pupura already recorded in medical history' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 19:37:58
User opened query 'Bruising is noted on the PE, should this be captured as an AE?' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 18:52:14
DataPoint Verified.		28 Sep 2020 18:50:37
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:18

US3182227

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:36:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:37
User entered '08 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:18

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:57:22
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:57:22
User entered empty.	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:57:22
User entered empty.	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:57:22
User entered '8 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:57:22
User entered '09:32'	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '8 Sep 2020 09:32'	System	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 06:33:58
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'confirmed per PI injection was to be given in right arm at this visit' (Site from System).	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 19:24:06
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 18:57:22
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	08 Sep 2020 13:40:04
User entered 'Right Arm (RIGHT ARM)'	Brooke Glivar (b) (4) (b) (4)	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
DataPoint Verified.		28 Sep 2020 18:57:22
User entered 'ONCE'	System	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:36:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 13:40:04

US3182227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:42

US3182227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:45
User entered '08 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:42

US3182227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:45
User entered '09:06'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:42

US3182227

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '08 Sep 2020 09:06'	System	10 Sep 2020 19:01:42

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:56
User entered '08 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:56
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:56
User entered '09:00'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:36:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered '08 Sep 2020 09:00'	System	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:58:56
User entered empty.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:36:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered empty.	System	10 Sep 2020 19:01:32

US3182227

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:59:02
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 19:01:46

US3182227

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:15
User entered 'I'	System	10 Sep 2020 19:01:46

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:03:21', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9451c756-4676-4edd-8cb5-02174e3c32c9' User entered 'Yes (Y)'	System	08 Sep 2020 14:03:57
	System	08 Sep 2020 14:03:57

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:03:47', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9451c756-4676-4edd-8cb5-02174e3c32c9' User entered '98.3'	System	08 Sep 2020 14:03:57
	System	08 Sep 2020 14:03:57

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:03:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9451c756-4676-4edd-8cb5-02174e3c32c9' User entered 'No (N)'	System	08 Sep 2020 14:03:57
	System	08 Sep 2020 14:03:57

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:03:55', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9451c756-4676-4edd-8cb5-02174e3c32c9' User entered '08 Sep 2020 10:03'	System	08 Sep 2020 14:03:57
	System	08 Sep 2020 14:03:57

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 09:52'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 12:22'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T16:59:58', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '533e5884-d3f6-4a14-ab8d-55878ff0b303' User entered 'Yes (Y)'	System	15 Sep 2020 22:39:14
	System	15 Sep 2020 22:39:14

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:04', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '533e5884-d3f6-4a14-ab8d-55878ff0b303' User entered '98.7'	System	15 Sep 2020 22:39:14
	System	15 Sep 2020 22:39:14

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:07', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '533e5884-d3f6-4a14-ab8d-55878ff0b303'	System	15 Sep 2020 22:39:14
User entered 'No (N)'	System	15 Sep 2020 22:39:14

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:10', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '533e5884-d3f6-4a14-ab8d-55878ff0b303' User entered '08 Sep 2020 17:00'	System	15 Sep 2020 22:39:14
	System	15 Sep 2020 22:39:14

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 13:17'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 2'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:26', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '7bdf350d-f314-4749-b245-c62eecadd585' User entered 'Yes (Y)'	System	15 Sep 2020 22:19:45
	System	15 Sep 2020 22:19:45

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:31', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '7bdf350d-f314-4749-b245-c62eecadd585' User entered '98.2'	System	15 Sep 2020 22:19:45
	System	15 Sep 2020 22:19:45

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:34', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '7bdf350d-f314-4749-b245-c62eecadd585'	System	15 Sep 2020 22:19:45
User entered 'No (N)'	System	15 Sep 2020 22:19:45

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:36', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '7bdf350d-f314-4749-b245-c62eecadd585' User entered '09 Sep 2020 18:43'	System	15 Sep 2020 22:19:45
	System	15 Sep 2020 22:19:45

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 3'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '694da92b-94dc-4645-9433-d1c55a09af88' User entered 'Yes (Y)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:38', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '694da92b-94dc-4645-9433-d1c55a09af88' User entered '98.2'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:40', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '694da92b-94dc-4645-9433-d1c55a09af88' User entered 'No (N)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:43', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '694da92b-94dc-4645-9433-d1c55a09af88' User entered '10 Sep 2020 18:53'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 4'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:28:56', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1d136554-5bd9-466e-bfbf-383b13c3b30d' User entered 'Yes (Y)'	System	03 Dec 2020 18:52:11
	System	03 Dec 2020 18:52:11

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:02', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1d136554-5bd9-466e-bfbf-383b13c3b30d' User entered '98.1'	System	03 Dec 2020 18:52:11
	System	03 Dec 2020 18:52:11

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:04', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1d136554-5bd9-466e-bfbf-383b13c3b30d' User entered 'No (N)'	System	03 Dec 2020 18:52:11
	System	03 Dec 2020 18:52:11

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:06', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1d136554-5bd9-466e-bfbf-383b13c3b30d' User entered '11 Sep 2020 16:29'	System	03 Dec 2020 18:52:11
	System	03 Dec 2020 18:52:11

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 5'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:20', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'de710c13-6f6f-4a80-93c4-0f380c9f2e6a' User entered 'Yes (Y)'	System	03 Dec 2020 18:52:15
	System	03 Dec 2020 18:52:15

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'de710c13-6f6f-4a80-93c4-0f380c9f2e6a' User entered '98.3'	System	03 Dec 2020 18:52:15
	System	03 Dec 2020 18:52:15

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:27', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'de710c13-6f6f-4a80-93c4-0f380c9f2e6a' User entered 'No (N)'	System	03 Dec 2020 18:52:15
	System	03 Dec 2020 18:52:15

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:29', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'de710c13-6f6f-4a80-93c4-0f380c9f2e6a' User entered '12 Sep 2020 18:11'	System	03 Dec 2020 18:52:15
	System	03 Dec 2020 18:52:15

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 6'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:40', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e48a7fd-5d38-4695-aedf-5fb6e1d09a8e' User entered 'Yes (Y)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:44', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e48a7fd-5d38-4695-aedf-5fb6e1d09a8e' User entered '98.3'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:46', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e48a7fd-5d38-4695-aedf-5fb6e1d09a8e' User entered 'No (N)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:49', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e48a7fd-5d38-4695-aedf-5fb6e1d09a8e' User entered '13 Sep 2020 16:33'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 7'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:12', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6dc60106-2258-4dd6-ae3-eea5ae395095' User entered 'Yes (Y)'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:17', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6dc60106-2258-4dd6-ae3-eea5ae395095' User entered '98.3'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:20', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6dc60106-2258-4dd6-ae3-eea5ae395095' User entered 'No (N)'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6dc60106-2258-4dd6-ae3-eea5ae395095' User entered '14 Sep 2020 16:11'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:06', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'aae8a522-fa07-4943-b5ce-3d4a3a6582ee' User entered 'None (1)'	System	08 Sep 2020 14:04:39
	System	08 Sep 2020 14:04:39

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:26', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'aae8a522-fa07-4943-b5ce-3d4a3a6582ee' User entered 'No (N)'	System	08 Sep 2020 14:04:39
	System	08 Sep 2020 14:04:39

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:29', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'aae8a522-fa07-4943-b5ce-3d4a3a6582ee' User entered 'No (N)'	System	08 Sep 2020 14:04:39
	System	08 Sep 2020 14:04:39

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'aae8a522-fa07-4943-b5ce-3d4a3a6582ee' User entered 'None (1)'	System	08 Sep 2020 14:04:39
	System	08 Sep 2020 14:04:39

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'aae8a522-fa07-4943-b5ce-3d4a3a6582ee' User entered '08 Sep 2020 10:04'	System	08 Sep 2020 14:04:39
	System	08 Sep 2020 14:04:39

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 09:52'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 12:22'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:14', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '22833517-9b73-43b3-a7f9-bea116771390' User entered 'None (1)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:16', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '22833517-9b73-43b3-a7f9-bea116771390' User entered 'No (N)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:18', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '22833517-9b73-43b3-a7f9-bea116771390' User entered 'No (N)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:20', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '22833517-9b73-43b3-a7f9-bea116771390' User entered 'None (1)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '22833517-9b73-43b3-a7f9-bea116771390' User entered '08 Sep 2020 17:00'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 13:17'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 2'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:40', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a529037-5f84-426a-aedd-3cf436493b64'	System	15 Sep 2020 22:19:51
User entered 'None (1)'	System	15 Sep 2020 22:19:51

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:42', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a529037-5f84-426a-aedd-3cf436493b64' User entered 'No (N)'	System	15 Sep 2020 22:19:51
	System	15 Sep 2020 22:19:51

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:44', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a529037-5f84-426a-aedd-3cf436493b64' User entered 'No (N)'	System	15 Sep 2020 22:19:51
	System	15 Sep 2020 22:19:51

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:45', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a529037-5f84-426a-aedd-3cf436493b64'	System	15 Sep 2020 22:19:51
User entered 'None (1)'	System	15 Sep 2020 22:19:51

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9a529037-5f84-426a-aedd-3cf436493b64' User entered '09 Sep 2020 18:43'	System	15 Sep 2020 22:19:51
	System	15 Sep 2020 22:19:51

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 3'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:47', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8574aece-3f10-4ee2-b052-048d3ea905e0' User entered 'None (1)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8574aece-3f10-4ee2-b052-048d3ea905e0' User entered 'No (N)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8574aece-3f10-4ee2-b052-048d3ea905e0' User entered 'No (N)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:54', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8574aece-3f10-4ee2-b052-048d3ea905e0' User entered 'None (1)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:53:56', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '8574aece-3f10-4ee2-b052-048d3ea905e0' User entered '10 Sep 2020 18:53'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 4'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:09', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6759f12d-364e-4258-b1a8-d035ccd5a77e' User entered 'None (1)'	System	03 Dec 2020 18:52:12
	System	03 Dec 2020 18:52:12

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6759f12d-364e-4258-b1a8-d035ccd5a77e' User entered 'No (N)'	System	03 Dec 2020 18:52:12
	System	03 Dec 2020 18:52:12

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:13', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6759f12d-364e-4258-b1a8-d035ccd5a77e' User entered 'No (N)'	System	03 Dec 2020 18:52:12
	System	03 Dec 2020 18:52:12

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:15', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6759f12d-364e-4258-b1a8-d035ccd5a77e' User entered 'None (1)'	System	03 Dec 2020 18:52:12
	System	03 Dec 2020 18:52:12

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:18', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '6759f12d-364e-4258-b1a8-d035ccd5a77e' User entered '11 Sep 2020 16:29'	System	03 Dec 2020 18:52:12
	System	03 Dec 2020 18:52:12

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 5'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e036d57-b2dc-407d-9f90-65f1fe702cc6'	System	03 Dec 2020 18:52:16
User entered 'None (1)'	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e036d57-b2dc-407d-9f90-65f1fe702cc6' User entered 'No (N)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:38', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e036d57-b2dc-407d-9f90-65f1fe702cc6' User entered 'No (N)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:40', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e036d57-b2dc-407d-9f90-65f1fe702cc6'	System	03 Dec 2020 18:52:16
User entered 'None (1)'	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:42', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '4e036d57-b2dc-407d-9f90-65f1fe702cc6' User entered '12 Sep 2020 18:11'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 6'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9889526b-136b-4f43-ad31-a09552a16662'	System	03 Dec 2020 18:52:17
User entered 'None (1)'	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:54', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9889526b-136b-4f43-ad31-a09552a16662' User entered 'No (N)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:56', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9889526b-136b-4f43-ad31-a09552a16662' User entered 'No (N)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:33:58', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9889526b-136b-4f43-ad31-a09552a16662'	System	03 Dec 2020 18:52:17
User entered 'None (1)'	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:00', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9889526b-136b-4f43-ad31-a09552a16662' User entered '13 Sep 2020 16:34'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 7'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:26', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e2ba5774-590b-4869-8906-83b93af56e0f' User entered 'None (1)'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:28', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e2ba5774-590b-4869-8906-83b93af56e0f' User entered 'No (N)'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:30', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e2ba5774-590b-4869-8906-83b93af56e0f' User entered 'No (N)'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:31', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e2ba5774-590b-4869-8906-83b93af56e0f' User entered 'None (1)'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:33', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'e2ba5774-590b-4869-8906-83b93af56e0f' User entered '14 Sep 2020 16:11'	System	03 Dec 2020 18:52:19
	System	03 Dec 2020 18:52:19

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:40', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered 'None (0)'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:42', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered 'None (0)'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:44', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered 'None (0)'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:46', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered 'None (0)'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered 'None (0)'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered 'None (0)'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:54', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered 'No (N)'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T10:04:57', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '42d9ad23-d7f6-4d8c-8ce7-01825e7d3f6f' User entered '08 Sep 2020 10:04'	System	08 Sep 2020 14:04:59
	System	08 Sep 2020 14:04:59

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 09:52'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 12:22'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:27', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered 'None (0)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:28', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered 'None (0)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:30', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered 'None (0)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered 'None (0)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:34', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered 'None (0)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered 'None (0)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:38', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered 'No (N)'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-08T17:00:41', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'c8679eda-f9eb-4b8d-9103-77131bc408f0' User entered '08 Sep 2020 17:00'	System	03 Dec 2020 18:52:09
	System	03 Dec 2020 18:52:09

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '08 Sep 2020 13:17'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 2'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:55', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered 'None (0)'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:57', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered 'None (0)'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:43:59', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered 'None (0)'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:44:01', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered 'None (0)'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:44:02', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered 'None (0)'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:44:04', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered 'None (0)'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:44:07', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered 'No (N)'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-09T18:44:09', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '0ce74a19-7581-42d4-bbce-fd692c5d357e' User entered '09 Sep 2020 18:44'	System	15 Sep 2020 22:20:19
	System	15 Sep 2020 22:20:19

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 3'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:02', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered 'None (0)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:04', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered 'None (0)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:05', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered 'None (0)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:07', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered 'None (0)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:09', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered 'None (0)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:10', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered 'None (0)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:13', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered 'No (N)'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-10T18:54:17', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '9b90b493-ed9f-4371-a37b-129b8359478f' User entered '10 Sep 2020 18:54'	System	03 Dec 2020 18:52:10
	System	03 Dec 2020 18:52:10

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 4'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:21', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered 'None (0)'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:22', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered 'None (0)'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:24', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered 'None (0)'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:25', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered 'None (0)'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:27', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered 'None (0)'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:29', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered 'None (0)'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:32', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered 'No (N)'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-11T16:29:34', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '82331abe-492a-47f9-8c4b-4d01ab9e32f7' User entered '11 Sep 2020 16:29'	System	03 Dec 2020 18:52:14
	System	03 Dec 2020 18:52:14

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 5'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:45', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered 'None (0)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:47', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered 'None (0)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered 'None (0)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:50', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered 'None (0)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:52', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered 'None (0)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:53', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered 'None (0)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:56', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered 'No (N)'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-12T18:11:59', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '85e8f1b0-35e8-427e-9eaf-407ca4495415' User entered '12 Sep 2020 18:11'	System	03 Dec 2020 18:52:16
	System	03 Dec 2020 18:52:16

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 6'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:03', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered 'None (0)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:05', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered 'None (0)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:06', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered 'None (0)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:08', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered 'None (0)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:09', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered 'None (0)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered 'None (0)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:13', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered 'No (N)'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-13T16:34:15', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'a7213f1f-a61a-42d1-baff-8b975a883829' User entered '13 Sep 2020 16:34'	System	03 Dec 2020 18:52:17
	System	03 Dec 2020 18:52:17

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
Data entry locked.	System	08 Sep 2020 13:40:04
User entered 'Day 7'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:37', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered 'None (0)'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:38', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered 'None (0)'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:40', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered 'None (0)'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:41', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered 'None (0)'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:43', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered 'None (0)'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:44', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered 'None (0)'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

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 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:46', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered 'No (N)'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-09-14T16:11:48', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'd1c0c16f-0973-4bc8-95b2-a20432c29167' User entered '14 Sep 2020 16:11'	System	03 Dec 2020 18:52:20
	System	03 Dec 2020 18:52:20

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:40:04

US3182227

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:36:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:15:02
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:40:04

US3182227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:41:15
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:39
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 17:54:53

US3182227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:41:15
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:39
User entered '15 Sep 2020'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 17:54:53

US3182227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:41:15
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:39
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 17:54:53

US3182227

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:41:15
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:39
User entered empty.	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 17:54:53

US3182227

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:41:15
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:23:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:48
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 17:54:57

US3182227

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:41:15
User entered 'I'	System	15 Sep 2020 17:54:57

US3182227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:05:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:56
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:45:21

US3182227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:05:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:56
User entered '22 Sep 2020'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:45:21

US3182227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:05:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:56
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:45:21

US3182227

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:05:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:35:56
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:45:21

US3182227

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:05:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:36:02
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:45:25

US3182227

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:05:16
User entered 'I'	System	24 Sep 2020 15:45:25

US3182227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:52
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:01:17
User entered 'Yes (Y)'	Alec Ireland (b) (4)	01 Oct 2020 17:22:02
	(b) (4)	

US3182227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:52
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:01:17
User entered '29 Sep 2020'	Alec Ireland (b) (4)	01 Oct 2020 17:22:02
	(b) (4)	

US3182227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:52
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:01:17
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	01 Oct 2020 17:22:02
	(b) (4)	

US3182227

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:52
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:01:17
User entered empty.	Alec Ireland (b) (4)	01 Oct 2020 17:22:02
	(b) (4)	

US3182227

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:52
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:01:23
User entered 'Yes (Y)'	Alec Ireland (b) (4)	01 Oct 2020 17:23:15
	(b) (4)	

US3182227

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:19:52
User entered 'I'	System	01 Oct 2020 17:23:15

US3182227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
User closed query 'Please complete continuing page for this visit. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:52:09
Query 'Please complete continuing page for this visit. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	01 Feb 2021 18:34:28
User opened query 'Please complete continuing page for this visit. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 20:08:09
DataPoint Verified.		08 Dec 2020 17:33:04
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 15:50:18

US3182227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:33:04
User entered empty.	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 15:50:18

US3182227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:33:04
User entered empty.	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 15:50:18

US3182227

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered 'VISIT3'	System	24 Nov 2020 15:50:18

US3182227

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		18 Mar 2021 16:36:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User closed query 'Please clarify as diary was completed 31Jan2021. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:48:33
Query 'Please clarify as diary was completed 31Jan2021. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:21:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:20:38
User opened query 'Please clarify as diary was completed 31Jan2021. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 20:51:09
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:34:20

US3182227

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	26 Feb 2021 19:20:38
User entered empty.	System	01 Feb 2021 18:34:20

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 64'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 71'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 78'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 92'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 99'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

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Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered 'Day 106'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[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)
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US3182227

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 16:14:07

US3182227

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:48:08
Data entry locked.	System	07 Aug 2020 16:14:07
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 16:14:07

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-03T13:52:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f297c0d2-bd8c-4686-895b-3b974493b103' User entered 'Yes (Y)'	System	03 Dec 2020 18:52:47
	System	03 Dec 2020 18:52:47

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-03T13:52:15', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f297c0d2-bd8c-4686-895b-3b974493b103'	System	03 Dec 2020 18:52:47
User entered 'No (N)'	System	03 Dec 2020 18:52:47

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-03T13:52:18', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f297c0d2-bd8c-4686-895b-3b974493b103'	System	03 Dec 2020 18:52:47
User entered 'No (N)'	System	03 Dec 2020 18:52:47

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-03T13:52:35', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f297c0d2-bd8c-4686-895b-3b974493b103'	System	03 Dec 2020 18:52:47
User entered 'No (N)'	System	03 Dec 2020 18:52:47

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-03T13:52:43', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: 'f297c0d2-bd8c-4686-895b-3b974493b103' User entered '03 Dec 2020 13:52:43'	System	03 Dec 2020 18:52:47
	System	03 Dec 2020 18:52:47

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-17T16:36:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '832c9311-42ca-46f9-9fa9-1215a1feaeda'	System	17 Dec 2020 21:36:27
User entered 'No (N)'	System	17 Dec 2020 21:36:27

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-17T16:36:14', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '832c9311-42ca-46f9-9fa9-1215a1feaeda'	System	17 Dec 2020 21:36:27
User entered 'No (N)'	System	17 Dec 2020 21:36:27

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2020-12-17T16:36:19', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '832c9311-42ca-46f9-9fa9-1215a1feaeda' User entered '17 Dec 2020 16:36:19'	System	17 Dec 2020 21:36:27
	System	17 Dec 2020 21:36:27

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-21T07:53:04', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '74f84b38-3347-44a3-98d4-6e5cdfdfc8b5'	System	21 Jan 2021 12:53:15
User entered 'No (N)'	System	21 Jan 2021 12:53:15

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-21T07:53:08', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '74f84b38-3347-44a3-98d4-6e5cdfdfc8b5'	System	21 Jan 2021 12:53:15
User entered 'No (N)'	System	21 Jan 2021 12:53:15

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-21T07:53:12', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '74f84b38-3347-44a3-98d4-6e5cdfdfc8b5'	System	21 Jan 2021 12:53:15
User entered '21 Jan 2021 07:53:12'	System	21 Jan 2021 12:53:15

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-25T06:41:08', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '60d7cb9d-2444-4ba7-86fb-d5871450d860' User entered 'No (N)'	System	25 Jan 2021 11:41:18
	System	25 Jan 2021 11:41:18

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-25T06:41:11', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '60d7cb9d-2444-4ba7-86fb-d5871450d860'	System	25 Jan 2021 11:41:18
User entered 'No (N)'	System	25 Jan 2021 11:41:18

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-25T06:41:16', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '60d7cb9d-2444-4ba7-86fb-d5871450d860' User entered '25 Jan 2021 06:41:16'	System	25 Jan 2021 11:41:18
	System	25 Jan 2021 11:41:18

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-31T07:42:18', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1708f0fc-273e-4423-ab68-b8eb7f4184c0'	System	31 Jan 2021 12:42:28
User entered 'No (N)'	System	31 Jan 2021 12:42:28

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-31T07:42:20', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1708f0fc-273e-4423-ab68-b8eb7f4184c0'	System	31 Jan 2021 12:42:28
User entered 'No (N)'	System	31 Jan 2021 12:42:28

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-01-31T07:42:23', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '1708f0fc-273e-4423-ab68-b8eb7f4184c0' User entered '31 Jan 2021 07:42:23'	System	31 Jan 2021 12:42:28
	System	31 Jan 2021 12:42:28

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-02-14T18:09:14', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '212ea135-e767-43c9-bdb6-03a3de6d0ddf' User entered 'No (N)'	System	14 Feb 2021 23:12:31
	System	14 Feb 2021 23:12:31

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-02-14T18:09:16', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '212ea135-e767-43c9-bdb6-03a3de6d0ddf'	System	14 Feb 2021 23:12:31
User entered 'No (N)'	System	14 Feb 2021 23:12:31

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80E604F2-5E61-4651-95F1-459AD1D9F51C)', Time: '2021-02-14T18:09:19', User OID: 'PatientReportedOutcome (US3182227)', ODM File OID: '212ea135-e767-43c9-bdb6-03a3de6d0ddf' User entered '14 Feb 2021 18:09:19'	System	14 Feb 2021 23:12:31
	System	14 Feb 2021 23:12:31

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:48:08

US3182227

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:36:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:48:08
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:48:08

US3182227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:34:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:03

US3182227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:34:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:03

US3182227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:34:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:03

US3182227

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:34:54
User closed query 'Please clarify as SAE had ended by that point. ' (Site from CRA).		25 Mar 2021 14:32:00
Query 'Please clarify as SAE had ended by that point. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 13:51:33
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 13:51:28
User entered 'NOT DONE DUE TO Site error' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 13:51:28
User opened query 'Please clarify as SAE had ended by that point. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 16:38:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'not done due to SAE'	(b) (4) Cassie Uminski (b) (4)	26 Feb 2021 19:22:03

US3182227

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		18 Mar 2021 16:38:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:09

US3182227

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered 'I'	System	26 Feb 2021 19:22:09

US3182227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:36

US3182227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Feb 2021 19:22:36
	(b) (4)	

US3182227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Feb 2021 19:22:36
	(b) (4)	

US3182227

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:50
User closed query 'Please clarify as SAE had ended by that point. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:35:08
DataPoint Verified.		25 Mar 2021 14:35:06
Query 'Please clarify as SAE had ended by that point. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 13:51:07
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 13:50:48
User entered 'NOT DONE DUE TO Site error' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 13:50:48
User opened query 'Please clarify as SAE had ended by that point. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 16:38:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'not done due to SAE'	(b) (4) Cassie Uminski (b) (4)	26 Feb 2021 19:22:36

US3182227

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		18 Mar 2021 16:38:51
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:43

US3182227

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered 'I'	System	26 Feb 2021 19:22:43

US3182227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:56

US3182227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:56

US3182227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:22:56

US3182227

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:35:33
User closed query 'Please clarify as SAE had ended by that point. ' (Site from CRA).		25 Mar 2021 14:35:31
Query 'Please clarify as SAE had ended by that point. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 13:51:50
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 13:51:45
User entered 'NOT DONE DUE TO Site error' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 13:51:45
User opened query 'Please clarify as SAE had ended by that point. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 16:39:10
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'not done due to SAE'	(b) (4) Cassie Uminski (b) (4)	26 Feb 2021 19:22:56
	(b) (4)	

US3182227

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		18 Mar 2021 16:39:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:23:11

US3182227

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered 'I'	System	26 Feb 2021 19:23:11

US3182227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:23:21

US3182227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:23:21

US3182227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		25 Mar 2021 14:35:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:23:21

US3182227

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:36:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:35:43
User closed query 'Please clarify as SAE had ended by that point. ' (Site from CRA).		25 Mar 2021 14:35:41
Query 'Please clarify as SAE had ended by that point. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 13:52:15
User entered 'NOT DONE DUE TO SITE ERROR' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 13:52:11
User entered 'NOT DONE DUE TO SITE ERRORU' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 13:52:07
Signature has been broken.	(b) (4)	25 Mar 2021 13:52:02
User entered 'NOT DONE DUE TO Site error' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 13:52:02
User opened query 'Please clarify as SAE had ended by that point. ' (Site from CRA).	(b) (4)	18 Mar 2021 16:39:29
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'not done due to SAE'	(b) (4) Cassie Uminski (b) (4)	26 Feb 2021 19:23:21

US3182227

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:55:55
User closed query 'Please complete the end of study page. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:47:56
Query 'Please complete the end of study page. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	26 Mar 2021 16:53:54
User opened query 'Please complete the end of study page. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 14:41:57
DataPoint Verified.		26 Mar 2021 14:41:32
User closed query 'Since subject has withdrawn consent should this be no? ' (Site from CRA).		26 Mar 2021 14:41:30
Query 'Since subject has withdrawn consent should this be no? ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:11:51
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:11:33
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:11:33
User opened query 'Since subject has withdrawn consent should this be no? ' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 14:36:38
DataPoint Un-verified.		25 Mar 2021 14:36:02
DataPoint Verified.		18 Mar 2021 16:39:34
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:23:28

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Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:36:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	25 Mar 2021 15:11:33
User entered 'I'	System	26 Feb 2021 19:23:28

US3182227

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

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:53:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:30:32

US3182227

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

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:53:12
User entered '20 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:30:32

US3182227

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

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:53:12
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:30:32

US3182227

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

Form: Visit Date

Generated On: 09 Jun 2021 15:36:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 18:30:32

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:25
User entered '20 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:41

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:24:47

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:41

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:24:47

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:25
User entered '20 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 18:33:21
User entered '21 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:41

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:25
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:41

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:25
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:41

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:25
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:41

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:25
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:41

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User entered 'I'	System	01 Feb 2021 18:32:41

US3182227

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

Form: Unblinding

Generated On: 09 Jun 2021 15:36:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User entered empty.	System	01 Feb 2021 18:32:41

US3182227

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:06

US3182227

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:52
User entered '20 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:06

US3182227

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:52
User entered '15:10'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:32:06

US3182227

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:36:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User entered '20 Jan 2021 15:10'	System	01 Feb 2021 18:32:06

US3182227

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:37
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:31:15

US3182227

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:37
User entered '20 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:31:15

US3182227

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:54:37
User entered '15:02'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 18:31:15

US3182227

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:36:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:43:01
User entered '20 Jan 2021 15:02'	System	01 Feb 2021 18:31:15

US3182227

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:36:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:30:03
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:03:30

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:34:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:34:42
Data point term sent to Coder	System	29 Oct 2020 16:18:50
User entered 'Left rotator cuff tear'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '25 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User entered empty.	System	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
DataPoint Verified.		30 Mar 2021 13:41:39
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'As subject had shoulder surgery on 07Oct2020 should this be updated?' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:15:30
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Jan 2021 18:05:14
DataPoint Un-verified.	Cassie Uminski (b) (4)	13 Jan 2021 18:05:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	13 Jan 2021 18:05:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	13 Jan 2021 18:05:01
Query 'As subject had shoulder surgery on 07Oct2020 should this be updated?' answered with 'Investigator is reviewing medical records and information will be updated ASAP' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 17:41:04
User opened query 'As subject had shoulder surgery on 07Oct2020 should this be updated?' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 18:23:45
DataPoint Verified.		30 Oct 2020 17:59:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
DataPoint Verified.		30 Mar 2021 13:41:41
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
DataPoint Un-verified.	Cassie Uminski (b) (4)	13 Jan 2021 18:05:01
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	13 Jan 2021 18:05:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4)	29 Oct 2020 16:18:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User entered empty.	System	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
Signature has been broken.	(b) (4)	30 Mar 2021 21:54:20
User signature succeeded.	Jennifer Gaston (b) (4)	27 Mar 2021 16:57:01
Signature has been broken.	(b) (4)	25 Mar 2021 13:56:18
User signature succeeded.	Cassie Uminski (b) (4)	18 Mar 2021 15:37:11
DataPoint Verified.	Mary Beth Manning	30 Oct 2020 17:59:28
User entered '0'	(b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
Signature has been broken.	(b) (4) Jennifer Gaston (b) (4)	22 Apr 2021 20:33:54
User signature succeeded.	(b) (4) Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Per DM CLR: RQ: Response noted, please keep this query open until the records are received and recorded in the appropriate eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:52
Query 'Per DM CLR: RQ: Response noted, please keep this query open until the records are received and recorded in the appropriate eCRF.' answered with 'Conmeds updated and added' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:08:08
User opened query 'Per DM CLR: RQ: Response noted, please keep this query open until the records are received and recorded in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:07:31
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:34:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Records not yet received' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 15:49:41
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 15:19:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '1'	Cassie Uminski (b) (4)	29 Oct 2020 16:18:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 13:42:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:54
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Con Procedures updated and added' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:08:18
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:07:45
User closed query 'Should this be yes as she had surgery on 07Oct2020?' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 22:15:36
Query 'Should this be yes as she had surgery on 07Oct2020?' answered with 'Investigator is reviewing medical records and information will be updated ASAP' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 17:40:58
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 17:34:23
User entered '1' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	13 Jan 2021 17:34:23
User opened query 'Should this be yes as she had surgery on 07Oct2020?' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 18:24:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
DataPoint Verified.		30 Mar 2021 13:42:42
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Has this resolved? ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:15:42
DataPoint Un-verified.	Cassie Uminski (b) (4)	13 Jan 2021 18:05:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	13 Jan 2021 18:05:01
Query 'Has this resolved? ' answered with 'Investigator is reviewing medical records and information will be updated ASAP' (Site from CRA).	Cassie Uminski (b) (4)	13 Jan 2021 17:40:56
User opened query 'Has this resolved? ' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 18:25:08
DataPoint Verified.		30 Oct 2020 17:59:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassie Uminski (b) (4)	29 Oct 2020 16:18:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User entered '0'	System	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40
User entered 'I'	System	29 Oct 2020 16:18:22

US3182227

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:19:38
Un-reviewed for Safety.		31 Mar 2021 15:01:44
DataPoint Un-verified.		31 Mar 2021 15:01:44
Signature has been broken.		31 Mar 2021 15:01:44
User entered empty; reason for change Data Entry Error		31 Mar 2021 15:01:44
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
Reviewed for Safety.		30 Oct 2020 13:05:46
User entered	System	30 Oct 2020 13:05:30
'USA-US075-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	30 Oct 2020 13:05:30

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:37:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 16:37:43
Data point term sent to Coder	System	29 Oct 2020 16:21:56
User entered 'Bradycardia'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '06 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User entered empty.	System	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
User closed query 'Should this be 06Oct2020? No bradycardia reported at hospital. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:19:52
DataPoint Verified.		31 Mar 2021 15:19:49
Query 'Should this be 06Oct2020? No bradycardia reported at hospital. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 21:52:53
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 21:52:47
User entered '06 Oct 2020' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 21:52:47
User opened query 'Should this be 06Oct2020? No bradycardia reported at hospital. ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 13:50:13
DataPoint Un-verified.		30 Mar 2021 13:49:09
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '09 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User entered empty.	System	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:19:57
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'SAE#2 PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:17:35
DataPoint Verified.		20 Nov 2020 20:28:29
Query 'SAE#2 PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4)	20 Nov 2020 19:31:17
DataPoint Un-verified.	Cassie Uminski (b) (4)	20 Nov 2020 19:31:12
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	20 Nov 2020 19:31:12
User opened query 'SAE#2 PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:30:02
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:20:01
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

US3182227

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:20:14
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User entered '0' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '1'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:20:16
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User entered empty; reason for change Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '06 Oct 2020'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:20:18
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User entered empty; reason for change Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '09 Oct 2020'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:20:20
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User entered empty; reason for change Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:01:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
DataPoint Verified.	(b) (4)	23 Apr 2021 13:24:36
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Un-verified.	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 19:32:04
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 19:32:04
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	22 Apr 2021 19:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 13:50:39
User closed query 'Per DM CLR re-query: Response noted as "Con procedure added". So please consider updating response to "Other action taken = Concomitant Procedure".' (Site from DM).	(b) (4)	22 Mar 2021 08:32:40
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
Query 'Per DM CLR re-query: Response noted as "Con procedure added". So please consider updating response to "Other action taken = Concomitant Procedure".' answered with 'Corrected.' (Site from DM).	Naqib Ahmad (b) (4)	17 Mar 2021 19:40:43
	(b) (4)	
DataPoint Un-verified.	Naqib Ahmad (b) (4)	17 Mar 2021 19:31:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 19:31:00
	(b) (4)	
User opened query 'Per DM CLR re-query: Response noted as "Con procedure added". So please consider updating response to "Other action taken = Concomitant Procedure".' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:58:17
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:58:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

None

Audit	User	Time (GMT)
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Con procedure added and updated' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:08:54
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:25:52
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User closed query 'Please update and add con meds from hospital. Aspirin is already added to con med log. ' (Site from CRA).		25 Mar 2021 14:41:55
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
Query 'Please update and add con meds from hospital. Aspirin is already added to con med log. ' answered with 'Will inactivate this line. ' (Site from CRA).	Naqib Ahmad (b) (4)	17 Mar 2021 19:29:53
	(b) (4)	
User opened query 'Please update and add con meds from hospital. Aspirin is already added to con med log. ' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 18:15:37
DataPoint Verified.		30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:56:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:23:35
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' answered with 'updated and confirmed' (Site from DM).	(b) (4) Jennifer Gaston (b) (4)	22 Apr 2021 19:32:31
DataPoint Un-verified.	Jennifer Gaston (b) (4)	22 Apr 2021 19:32:04
Signature has been broken.	(b) (4) Jennifer Gaston (b) (4)	22 Apr 2021 19:32:04
User entered '0' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	22 Apr 2021 19:32:04
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:32:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 14:02:30
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Un-verified.	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:31:00
User entered '1' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:31:00

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:25:42
User closed query 'Should rotator cuff repair be shoulder arthroplasty? ' (Site from CRA).		31 Mar 2021 16:25:40
User entered 'SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ARTHROPLASTY. FOLLOWING SURGERY HER HEART RATE DROPPED TO 30 AND SHE WAS TAKEN BY AMBULANCE TO ER. SHE WAS LATER ADMITTED DUE TO CARDIAC HISTORY FOR FULL WORK UP AND EVALUATION. SHE WAS DISCHARGED HOME ON 10/9/20. MEDICAL RECORDS PENDING.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:01:42
MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT HAD ROTATOR CUFF REPAIR SURGERY. IN POST OP- SUBJECT DEVELOPED BRADYCARDIA AND WAS TRANSFERRED TO THE HOSPITAL. UPON ADMISSION, THE SUBJECT UNDERWENT EKG, CHEST CT WITH CONTRAST, A CARDIAC CATHETERIZATION, AND A CHEST X-RAY. SUBJECT WAS DISCHARGED WITH INSTRUCTION TO FOLLOW UP.		
CARDIAC CATHETERIZATION- NO STENOSIS EKG- NORMAL, SINUS RHYTHM WITH SINUS ARRHYTHMIA INCOMPLETE RBBB (NONSPECIFIC EKG CHANGES) TROPONINS ARE NEGATIVE CT CHEST NEGATIVE FOR PE. After investigator review, it was deemed this is not a SAE.' reason for change: Data Entry Error		
Query 'Should rotator cuff repair be shoulder arthroplasty? ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 21:53:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 21:53:16
User entered 'SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT arthroplasty. FOLLOWING SURGERY HER HEART RATE DROPPED TO 30 AND SHE WAS TAKEN BY AMBULANCE TO ER. SHE WAS LATER ADMITTED DUE TO CARDIAC HISTORY FOR FULL WORK UP AND EVALUATION. SHE WAS DISCHARGED HOME ON 10/9/20. MEDICAL RECORDS PENDING.	Jennifer Gaston (b) (4)	30 Mar 2021 21:53:16
MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT HAD ROTATOR CUFF REPAIR SURGERY. IN POST OP- SUBJECT DEVELOPED BRADYCARDIA AND WAS TRANSFERRED TO THE HOSPITAL. UPON ADMISSION, THE SUBJECT UNDERWENT EKG, CHEST CT WITH CONTRAST, A CARDIAC CATHETERIZATION, AND A CHEST X-RAY. SUBJECT WAS DISCHARGED WITH INSTRUCTION TO FOLLOW UP.		
CARDIAC CATHETERIZATION- NO STENOSIS EKG- NORMAL, SINUS RHYTHM WITH SINUS ARRHYTHMIA INCOMPLETE RBBB (NONSPECIFIC EKG CHANGES) TROPONINS ARE NEGATIVE CT CHEST NEGATIVE FOR PE' reason for change: Data Entry Error		
User opened query 'Should rotator cuff repair be shoulder arthroplasty? ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 13:55:04
User closed query 'Per DM CLR: Narrative = TROPONINS. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		24 Mar 2021 09:39:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = UPON ADMISSION, THE SUBJECT UNDERWENT EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:39:16
User closed query 'Per DM CLR: Other Action Taken = None, however there is a ConProc (CARDIAC CATHETERIZATION) recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:38:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'PV Query: Please send the cardiac catheterization report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:09:25
Query 'Per DM CLR: Narrative = TROPONINS. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Corrected.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:41:02
Query 'Per DM CLR: Narrative = UPON ADMISSION, THE SUBJECT UNDERWENT EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'EKG has been added.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:36:02
Query 'Per DM CLR: Other Action Taken = None, however there is a ConProc (CARDIAC CATHETERIZATION) recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'Corrected.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:34:00
Query 'PV Query: Please send the cardiac catheterization report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'Unable to obtain as subject has withdrew her consent and has been dropped from this clinical trial. ' (Site from Safety).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:31:47

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = TROPONINS. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 02:01:45
User opened query 'Per DM CLR: Narrative = UPON ADMISSION, THE SUBJECT UNDERWENT EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		13 Mar 2021 02:01:38
User opened query 'Per DM CLR: Other Action Taken = None, however there is a ConProc (CARDIAC CATHETERIZATION) recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).		13 Mar 2021 02:00:52
User closed query 'Per DM CLR: SAE Narrative = FULL WORK UP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:57:08
User closed query 'Per DM CLR: SAE Narrative = SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ROTATOR CUFF REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		02 Mar 2021 07:55:45
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:47:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		01 Mar 2021 16:47:18

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'Associated pages (conmeds, conproc) updated with information' (Site from Safety).	Jennifer Gaston (b) (4)	28 Feb 2021 20:53:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Narrative updated' (Site from Safety).	Jennifer Gaston (b) (4)	28 Feb 2021 20:52:36
User entered 'SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ROTATOR CUFF REPAIR. FOLLOWING SURGERY HER HEART RATE DROPPED TO 30 AND SHE WAS TAKEN BY AMBULANCE TO ER. SHE WAS LATER ADMITTED DUE TO CARDIAC HISTORY FOR FULL WORK UP AND EVALUATION. SHE WAS DISCHARGED HOME ON 10/9/20. MEDICAL RECORDS PENDING.	Jennifer Gaston (b) (4)	28 Feb 2021 20:51:57
MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT HAD ROTATOR CUFF REPAIR SURGERY. IN POST OP- SUBJECT DEVELOPED BRADYCARDIA AND WAS TRANSFERRED TO THE HOSPITAL. UPON ADMISSION, THE SUBJECT UNDERWENT EKG, CHEST CT WITH CONTRAST, A CARDIAC CATHETERIZATION, AND A CHEST X-RAY. SUBJECT WAS DISCHARGED WITH INSTRUCTION TO FOLLOW UP.		
Cardiac Catheterization- no stenosis EKG- Normal, sinus rhythm with sinus arrhythmia incomplete RBBB (Nonspecific EKG changes) Troponins are negative CT Chest negative for PE' reason for change: Data Entry Error DataPoint Un-verified.		
	Jennifer Gaston (b) (4)	28 Feb 2021 20:41:11

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ROTATOR CUFF REPAIR. FOLLOWING SURGERY HER HEART RATE DROPPED TO 30 AND SHE WAS TAKEN BY AMBULANCE TO ER. SHE WAS LATER ADMITTED DUE TO CARDIAC HISTORY FOR FULL WORK UP AND EVALUATION. SHE WAS DISCHARGED HOME ON 10/9/20. MEDICAL RECORDS PENDING. Medical records received and reviewed. Subject had rotator cuff repair surgery. In post op- subject developed bradycardia and was transferred to the hospital. Upon admission, the subject underwent Chest CT with contrast, a cardiac catheterization, and a Chest X-Ray. Subject was discharged with instruction to follow up.' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	28 Feb 2021 20:41:11
Query 'Per DM CLR: SAE Narrative = FULL WORK UP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Procedures related to SAE updated to conproc page' (Site from DM).	Jennifer Gaston (b) (4)	28 Feb 2021 20:34:34
Query 'Per DM CLR: SAE Narrative = SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ROTATOR CUFF REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated con procedure page' (Site from DM).	Jennifer Gaston (b) (4)	28 Feb 2021 20:34:00
User opened query 'PV Query: Please send the cardiac catheterization report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 17:04:45
User opened query 'Per DM CLR: SAE Narrative = FULL WORK UP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:26:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ROTATOR CUFF REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:26:10
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 23:58:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		30 Nov 2020 23:57:55
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)	23 Nov 2020 20:24:52
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).		23 Nov 2020 20:24:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		23 Nov 2020 20:24:42
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 'Records were requested and site is still waiting to receive ' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 19:34:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'Records were requested and site is still waiting to receive ' (Site from Safety).	Cassie Uminski (b) (4)	20 Nov 2020 19:34:35
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Records were requested and site is still waiting to receive them' (Site from Safety).	Cassie Uminski (b) (4)	20 Nov 2020 19:33:48
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).	(b) (4), (b) (6)	05 Nov 2020 15:29:49
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:29:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:28:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Subject was at a surgery center on 10/6/20 for left rotator cuff repair. Following surgery her heart rate dropped to 30 and she was taken by ambulance to ER. She was later admitted due to cardiac History for full work up and evaluation. She was discharged home on 10/9/20. Medical records pending.'	Cassie Uminski (b) (4)	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User entered '0'	System	30 Mar 2021 22:01:21
User entered '1'	System	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User entered '1'	System	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:24
User entered '0'	System	29 Oct 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:27:45
Un-reviewed for Safety.		31 Mar 2021 15:02:22
DataPoint Un-verified.		31 Mar 2021 15:02:22
Signature has been broken.		31 Mar 2021 15:02:22
User entered empty; reason for change Data Entry Error		31 Mar 2021 15:02:22
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
Reviewed for Safety.		30 Oct 2020 13:06:29
User entered 'USA-US075-2020-mRNA-1273-P301000004'		30 Oct 2020 13:06:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:30:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:30:59
Data point term sent to Coder	System	29 Oct 2020 17:30:25
User entered 'SYNCOPE' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 17:29:29
Data point term sent to Coder	System	29 Oct 2020 16:23:58
User entered 'Sycope'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'PV Query: Please confirm start date as the case narrative reports not feeling well on "10/27/20".' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:44:51
Query 'PV Query: Please confirm start date as the case narrative reports not feeling well on "10/27/20".' answered with 'Correct as is' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:16:15
User opened query 'PV Query: Please confirm start date as the case narrative reports not feeling well on "10/27/20".' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:02:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '24 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User entered empty.	System	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
DataPoint Verified.		31 Mar 2021 16:27:53
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Per DM CLR: RQ: Response noted. Please review and update the date as this is unusual for SYNCOPE to have a duration of more than one day. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 08:29:03
Query 'Per DM CLR: RQ: Response noted. Please review and update the date as this is unusual for SYNCOPE to have a duration of more than one day. Otherwise, provide clarification.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:16:06
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:15:53
User entered '24 Oct 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	26 Feb 2021 19:15:53
User opened query 'Per DM CLR: RQ: Response noted. Please review and update the date as this is unusual for SYNCOPE to have a duration of more than one day. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:41:03
User closed query 'Per DM CLR: Please review the stop date recorded as it is not expected that SYNCOPE has a duration of more than a day. Effects may last for days but not this AE. Please record any effects of SYNCOPE if available. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:38:16
Query 'Per DM CLR: Please review the stop date recorded as it is not expected that SYNCOPE has a duration of more than a day. Effects may last for days but not this AE. Please record any effects of SYNCOPE if available. Otherwise, clarify.' answered with 'Waiting on Hospital Records' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 18:06:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the stop date recorded as it is not expected that SYNCOPE has a duration of more than a day. Effects may last for days but not this AE. Please record any effects of SYNCOPE if available. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 15:20:09
	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '26 Oct 2020'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User entered empty.	System	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:27:58
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:02
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:02
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:02
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:25:00
DataPoint Verified.		20 Nov 2020 20:28:48
DataPoint Un-verified.	Cassie Uminski (b) (4)	20 Nov 2020 19:35:30
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	20 Nov 2020 19:35:30
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4)	20 Nov 2020 19:35:11
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:31:32
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:28:02
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	30 Mar 2021 21:57:32
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	30 Mar 2021 21:57:02
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:02
Signature has been broken.	(b) (4) Jennifer Gaston (b) (4)	30 Mar 2021 21:57:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	30 Mar 2021 21:57:02
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:28:04
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User entered '0' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '1'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:28:06
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User entered empty; reason for change Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '24 Oct 2020'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:28:08
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User entered empty; reason for change Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '26 Oct 2020'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:28:09
DataPoint Un-verified.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User entered empty; reason for change Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 21:57:32
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'No (N)'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
DataPoint Verified.	(b) (4)	23 Apr 2021 13:26:53
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Un-verified.	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 20:17:35
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 20:17:35
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 20:17:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 16:28:19
User closed query 'Per DM CLR re-query: Response noted. However, conmed log line 7 (Start and stop date 24OCT2020) and conmed procedures have been reported within this time frame of AE. Please reconcile response to other action taken for conmed and conmed procedure field and update as appropriate, else clarify.' (Site from DM).	(b) (4)	22 Mar 2021 08:31:58
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
Query 'Per DM CLR re-query: Response noted. However, conmed log line 7 (Start and stop date 24OCT2020) and conmed procedures have been reported within this time frame of AE. Please reconcile response to other action taken for conmed and conmed procedure field and update as appropriate, else clarify.' answered with 'Corrected.' (Site from DM).	Naqib Ahmad (b) (4)	17 Mar 2021 19:42:20
	(b) (4)	
DataPoint Un-verified.	Naqib Ahmad (b) (4)	17 Mar 2021 19:42:12
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 19:42:12
	(b) (4)	

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Form: Adverse Events (3)

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None

Audit	User	Time (GMT)
User opened query 'Per DM CLR re-query: Response noted. However, conmed log line 7 (Start and stop date 24OCT2020) and conmed procedures have been reported within this time frame of AE. Please reconcile response to other action taken for conmed and conmed procedure field and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:10:19
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:10:19
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Confirmed' (Site from DM).	Cassie Uminski (b) (4)	26 Feb 2021 19:17:27
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:26:59
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'I'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).		26 Apr 2021 13:56:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:27:13
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' answered with 'confirmed- data updated' (Site from DM).	(b) (4) Jennifer Gaston (b) (4)	22 Apr 2021 20:17:54
DataPoint Un-verified.	Jennifer Gaston (b) (4)	22 Apr 2021 20:17:35
Signature has been broken.	(b) (4) Jennifer Gaston (b) (4)	22 Apr 2021 20:17:35
User entered '0' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	22 Apr 2021 20:17:35
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:32:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:28:28
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Un-verified.	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:42:12
User entered '1' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:42:12

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Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered '0'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26
	(b) (4)	

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Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User closed query 'Per DM CLR: Narrative = ORTHOSTATIC. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:56:27
User closed query 'Per DM CLR: Narrative = TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:56:25
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
Query 'Per DM CLR: Narrative = ORTHOSTATIC. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'confirmed per PI not an AE ' (Site from DM).	(b) (4) Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:20:59
Query 'Per DM CLR: Narrative = TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Per PI- no- tachycardia related to the dehydration, not an AE' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:20:09
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:28:40
User opened query 'Per DM CLR: Narrative = ORTHOSTATIC. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 03:08:18
User opened query 'Per DM CLR: Narrative = TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 03:08:12
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 21:58:04

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED NOT FEELING WELL ON 10/27/20, SHE HAD SYNCOPAL EPISODE AT HOME WITH HUSBAND PRESENT. HE CALLED 911 AND SHE WAS TAKEN BY AMBULANCE TO HOSPITAL WHERE SHE WAS ADMITTED FOR EVALUATION. SHE WAS DISCHARGED HOME ON 10/26/20. MEDICAL RECORDS PENDING. MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT PRESENTED TO ED FOR CONCERNS OF DEHYDRATIONS, DIZZINESS/LIGHTHEADEDNESS, DIARRHEA AND GENERALIZED WEAKNESS. SUBJECT STOPPED HER NARCOTIC PAIN MEDICATION AT HOME DUE TO CONSTIPATION. TOOK A LAXATIVE AND STARTED HAVING DIARRHEA. AN EKG WAS DONE IN THE ED, SHOWED TACHYCARDIA (149BPM). CT OF CHEST WAS NEGATIVE FOR PE. CT OF BRAIN SHOWED NO ACUTE INTRACRANIAL PROCESS. FOUND TO BE ORTHOSTATIC, GIVEN IV FLUIDS. ADMITTED FOR FURTHER EVALUATION. SUBJECT HAD A COVID NASOPHARYNGEAL SWAB ON 10/24/2020 WHICH RESULTED IN A NEGATIVE RESULT. After review with Investigator, it was deemed this was not a SAE.' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 21:58:04
User closed query 'Per DM CLR: Narrative = TOOK A LAXATIVE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:41:35
User closed query 'Per DM CLR: Narrative = SUBJECT STOPPED HER NARCOTIC PAIN MEDICATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		24 Mar 2021 09:41:32
User closed query 'Per DM CLR: Narrative = CONSTIPATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		24 Mar 2021 09:40:22

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = DEHYDRATIONS, DIZZINESS/LIGHTHEADEDNESS, DIARRHEA AND GENERALIZED WEAKNESS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:40:00
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:09:02
Query 'Per DM CLR: Narrative = CONSTIPATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Added as AE. ' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:33:41
Query 'Per DM CLR: Narrative = TOOK A LAXATIVE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Corrected.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:24:09
Query 'Per DM CLR: Narrative = SUBJECT STOPPED HER NARCOTIC PAIN MEDICATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Corrected.' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:14:56
Query 'Per DM CLR: Narrative = DEHYDRATIONS, DIZZINESS/LIGHTHEADEDNESS, DIARRHEA AND GENERALIZED WEAKNESS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Added. ' (Site from DM).	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:50:04

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Form: Adverse Events (3)

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[Narrative](#)

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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'This was sent. ' (Site from Safety).	Naqib Ahmad (b) (4)	17 Mar 2021 19:42:31
User opened query 'Per DM CLR: Narrative = TOOK A LAXATIVE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 02:02:37
User opened query 'Per DM CLR: Narrative = CONSTIPATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		13 Mar 2021 02:02:32
User opened query 'Per DM CLR: Narrative = SUBJECT STOPPED HER NARCOTIC PAIN MEDICATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		13 Mar 2021 02:02:25
User opened query 'Per DM CLR: Narrative = DEHYDRATIONS, DIZZINESS/LIGHTHEADEDNESS, DIARRHEA AND GENERALIZED WEAKNESS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		13 Mar 2021 02:02:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:46:21
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)	01 Mar 2021 16:46:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:45:33
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Narrative updated' (Site from Safety).	Jennifer Gaston (b) (4)	28 Feb 2021 21:14:04
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 'Updated narrative to reflect information' (Site from Safety).	Jennifer Gaston (b) (4)	28 Feb 2021 21:13:47

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED NOT FEELING WELL ON 10/27/20, SHE HAD SYNCOPAL EPISODE AT HOME WITH HUSBAND PRESENT. HE CALLED 911 AND SHE WAS TAKEN BY AMBULANCE TO HOSPITAL WHERE SHE WAS ADMITTED FOR EVALUATION. SHE WAS DISCHARGED HOME ON 10/26/20. MEDICAL RECORDS PENDING. MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT PRESENTED TO ED FOR CONCERNS OF DEHYDRATIONS, DIZZINESS/LIGHTHEADEDNESS, DIARRHEA AND GENERALIZED WEAKNESS. SUBJECT STOPPED HER NARCOTIC PAIN MEDICATION AT HOME DUE TO CONSTIPATION. TOOK A LAXATIVE AND STARTED HAVING DIARRHEA. AN EKG WAS DONE IN THE ED, SHOWED TACHYCARDIA (149BPM). CT OF CHEST WAS NEGATIVE FOR PE. CT OF BRAIN SHOWED NO ACUTE INTRACRANIAL PROCESS. FOUND TO BE ORTHOSTATIC, GIVEN IV FLUIDS. ADMITTED FOR FURTHER EVALUATION. Subject had a COVID Nasopharyngeal Swab on 10/24/2020 which resulted in a negative result.' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:13:04
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'Con proc eCRF updated' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:10:59
DataPoint Un-verified.	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:10:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED NOT FEELING WELL ON 10/27/20, SHE HAD SYNCOPAL EPISODE AT HOME WITH HUSBAND PRESENT. HE CALLED 911 AND SHE WAS TAKEN BY AMBULANCE TO HOSPITAL WHERE SHE WAS ADMITTED FOR EVALUATION. SHE WAS DISCHARGED HOME ON 10/26/20. MEDICAL RECORDS PENDING. Medical records received and reviewed. Subject presented to ED for concerns of dehydrations, dizziness/lightheadedness, diarrhea and generalized weakness. Subject stopped her narcotic pain medication at home due to constipation. Took a laxative and started having diarrhea. An EKG was done in the ED, showed tachycardia (149bpm). CT of Chest was negative for PE. CT of Brain showed no acute intracranial process. Found to be orthostatic, given IV fluids. Admitted for further evaluation.'	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:10:41
reason for change: Data Entry Error User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:03:20
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).		01 Dec 2020 00:02:59
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).		01 Dec 2020 00:02:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		01 Dec 2020 00:02:01

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm start date as the case narrative reports not feeling well on "10/27/20".' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:25:09
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' (Site from Safety).		23 Nov 2020 20:25:07
User closed query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		23 Nov 2020 20:25:04
Query 'PV Query: Please confirm start date as the case narrative reports not feeling well on "10/27/20".' answered with 'Records still pending' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 19:37:00
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so' answered with 'Records still pending' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 19:36:56
Query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Records still pending' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 19:36:51
User opened query 'PV Query: Please confirm start date as the case narrative reports not feeling well on "10/27/20".' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:31:14
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 Nov 2020 15:30:42

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
User opened query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:17
	(b) (4), (b) (6)	30 Oct 2020 17:59:28
User entered 'Subject reported not feeling well on 10/27/20, she had syncopal episode at home with husband present. He called 911 and she was taken by ambulance to hospital where she was admitted for evaluation. She was discharged home on 10/26/20. Medical records pending.'	Cassie Uminski (b) (4)	29 Oct 2020 16:23:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User entered '0'	System	30 Mar 2021 21:57:02
User entered '1'	System	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User entered 'I'	System	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:39:05
User entered '0'	System	29 Oct 2020 16:23:26

US3182227

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:16
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Atelectasis, LLT: Atelectasis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 12:27:15
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 12:27:15
Data point term sent to Coder	System	28 Feb 2021 20:55:41
User entered 'Infrahilar Atelectasis'	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

US3182227

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:19
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
User closed query 'It looks like this should be medically attended from the DC summary on 09Oct2020. Please clarify. Page 64 of 87. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:38:01
Query 'It looks like this should be medically attended from the DC summary on 09Oct2020. Please clarify. Page 64 of 87. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:54:13
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:53:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:53:56
User opened query 'It looks like this should be medically attended from the DC summary on 09Oct2020. Please clarify. Page 64 of 87. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:46:05
User signature succeeded.	Mary Beth Manning (b) (4)	18 Mar 2021 15:37:11
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:27
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:29
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:31
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '06 Oct 2020'	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:34
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	28 Feb 2021 20:55:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Feb 2021 20:55:25
User entered empty; reason for change Data Entry Error	Jennifer Gaston (b) (4)	28 Feb 2021 20:55:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Feb 2021 20:54:57
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Feb 2021 20:54:57
User entered 'un:un' (non-conformant).	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	28 Feb 2021 20:55:25
User entered '06 Oct 2020 UN:UN' (non-conformant).	System	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:36
User closed query 'Is there a resolution? CT at Hillcrest scheduled for 12Nov2020. ' (Site from CRA).		19 Mar 2021 14:03:39
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
Query 'Is there a resolution? CT at Hillcrest scheduled for 12Nov2020. ' answered with 'Unable to obtain. ' (Site from CRA).	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 20:39:12
User opened query 'Is there a resolution? CT at Hillcrest scheduled for 12Nov2020. ' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 18:04:11
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:39
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:41
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:43
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:44
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:46
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

US3182227

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:48
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:50
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:52
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:56
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:29:57
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:00
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:02
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

US3182227

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:04
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

US3182227

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:06
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:08
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
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	28 Feb 2021 20:55:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	28 Feb 2021 20:55:25
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Gaston (b) (4)	28 Feb 2021 20:55:25
User entered empty.	(b) (4)	
	System	28 Feb 2021 20:54:57
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:10
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
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	28 Feb 2021 20:55:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	28 Feb 2021 20:55:25
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Gaston (b) (4)	28 Feb 2021 20:55:25
User entered empty.	(b) (4)	
	System	28 Feb 2021 20:54:57
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:11
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Feb 2021 20:55:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Feb 2021 20:55:25
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	28 Feb 2021 20:55:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Feb 2021 20:54:57
User entered empty.	System	28 Feb 2021 20:54:57
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:14
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'l'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:15
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:17
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:19
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:20
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:30:22
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:54:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '0'	System	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	25 Mar 2021 13:53:56
User entered '0'	System	28 Feb 2021 20:54:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:08
Reviewed for Safety.		31 Mar 2021 15:09:52
User entered 'USA-US075-2020-mRNA-1273-P301000004'		31 Mar 2021 15:09:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:10
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 19:55:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 19:55:48
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 19:54:40
User entered 'Dehydration'	Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:12
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Yes (Y)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:13
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:15
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:18
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '24 Oct 2020'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:20
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:25
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:26
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User entered '26 Oct 2020' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '24 Oct 2020'	Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:30
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:32
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User entered 'Grade 4 (Grade 4)' reason for change:	(b) (4)	
Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User signature succeeded.	(b) (4)	
	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:34
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:36
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:37
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:41
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).	System	30 Mar 2021 22:09:04
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 by data change (Site from System).	System	30 Mar 2021 22:09:04
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	30 Mar 2021 22:08:45
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User entered '1' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User signature succeeded.	(b) (4) Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:44
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User entered '24 Oct 2020' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:46
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:10:49
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:09:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	30 Mar 2021 22:09:04
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:50
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:52
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:54
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

US3182227

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:10:55
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:11:03
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:11:09
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:11:11
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:08:45
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'None (NONE)'	(b) (4) Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:11:15
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Mar 2021 19:55:40
User entered '0'	System	17 Mar 2021 19:54:28
	Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:11:17
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 19:55:40
	(b) (4)	
User entered '0'	Naqib Ahmad (b) (4)	17 Mar 2021 19:54:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:11:19
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:11:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 15:12:08
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User closed query 'Per DM CLR: Narrative = CONSTIPATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:57:15
User closed query 'Per DM CLR: Narrative = TOOK A LAXATIVE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:56:51
User closed query 'Per DM CLR: Narrative = DIARRHEA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:56:48
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
Query 'Per DM CLR: Narrative = TOOK A LAXATIVE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not for the medically attended event, data is correct as is ' (Site from DM).	(b) (4) Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:26:53
Query 'Per DM CLR: Narrative = DIARRHEA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Not a medically attended event, thus not reportable ' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:26:10
Query 'Per DM CLR: Narrative = CONSTIPATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Subject has a HX of constipation- not an AE per PI' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:22:38
User opened query 'Per DM CLR: Narrative = TOOK A LAXATIVE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:33:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = CONSTIPATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:33:54
User opened query 'Per DM CLR: Narrative = DIARRHEA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		03 Apr 2021 05:33:47
DataPoint Verified.		31 Mar 2021 15:12:10
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Mar 2021 22:11:56
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Mar 2021 22:11:56
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:11:56

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED NOT FEELING WELL ON 10/24/20, SHE HAD SYNCOPAL EPISODE AT HOME WITH HUSBAND PRESENT. HE CALLED 911 AND SHE WAS TAKEN BY AMBULANCE TO HOSPITAL WHERE SHE WAS ADMITTED FOR EVALUATION. SHE WAS DISCHARGED HOME ON 10/26/20. MEDICAL RECORDS PENDING. MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT PRESENTED TO ED FOR CONCERNS OF DEHYDRATIONS, DIZZINESS/LIGHTHEADEDNESS, DIARRHEA AND GENERALIZED WEAKNESS. SUBJECT STOPPED HER NARCOTIC PAIN MEDICATION AT HOME DUE TO CONSTIPATION. TOOK A LAXATIVE AND STARTED HAVING DIARRHEA. AN EKG WAS DONE IN THE ED, SHOWED TACHYCARDIA (149BPM). CT OF CHEST WAS NEGATIVE FOR PE. CT OF BRAIN SHOWED NO ACUTE INTRACRANIAL PROCESS. FOUND TO BE ORTHOSTATIC, GIVEN IV FLUIDS. ADMITTED FOR FURTHER EVALUATION. SUBJECT HAD A COVID NASOPHARYNGEAL SWAB ON 10/24/2020 WHICH RESULTED IN A NEGATIVE RESULT. Although the discharge summary says generalized weakness, after Investigator's review of records, it is indicated that the weakness was due to the dehydration treated with IV fluids.' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:11:56
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Mar 2021 22:08:45
User signature succeeded.	Mary Beth Manning (b) (4)	18 Mar 2021 15:37:11
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	30 Mar 2021 22:08:45
User entered '0'	System	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	17 Mar 2021 19:54:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '0'	System	30 Mar 2021 22:09:04

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:07
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness generalized - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 20:02:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:02:48
Data point term sent to Coder	System	17 Mar 2021 20:01:51
User entered 'Generalized Weakness'	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:08
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Yes (Y)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:10
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:12
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:13
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '24 Oct 2020'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:15
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
User entered empty.	System	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:16
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '24 Oct 2020'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:23
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
User entered empty.	System	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:27
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Naqib Ahmad (b) (4)	17 Mar 2021 20:01:39
	(b) (4)	

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:31
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:33
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:35
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:39
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:41
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:42
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:44
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:46
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:48
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:50
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:51
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:53
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:55
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:14:57
User closed query 'Since this is after both doses should it be NA instead of none? ' (Site from CRA).		30 Mar 2021 13:02:40
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
Query 'Since this is after both doses should it be NA instead of none? ' answered with 'Updated' (Site from CRA).	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 17:25:06
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 17:24:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 17:24:52
User opened query 'Since this is after both doses should it be NA instead of none? ' (Site from CRA).	(b) (4), (b) (6) (b) (4)	25 Mar 2021 17:30:41
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'None (NONE)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:15:04
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	17 Mar 2021 20:01:51
User entered '1' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 20:01:51
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	17 Mar 2021 20:01:39
User entered '0'	System	17 Mar 2021 20:01:39
	Naqib Ahmad (b) (4)	17 Mar 2021 20:01:39
	(b) (4)	

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:15:06
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:15:07
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '0'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:15:10
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:15:12
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
DataPoint Verified.		31 Mar 2021 15:15:14
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
User entered '0'	System	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22
User entered 'I'	System	17 Mar 2021 20:01:39

US3182227

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:38:22

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:26
Reviewed for Safety.		31 Mar 2021 15:10:28
User entered 'USA-US075-2020-mRNA-1273-P301000004'		31 Mar 2021 15:10:24

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:08:30
User closed query 'Please specify type of chest pain e.g. cardiac, muscular. ' (Site from CRA).		15 Apr 2021 20:03:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Chest pain (non-cardiac) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 20:59:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 20:59:05
Query 'Please specify type of chest pain e.g. cardiac, muscular. ' answered with 'corrected.' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	13 Apr 2021 20:58:24
Data point term sent to Coder	System	13 Apr 2021 20:58:22
Coding entries removed.	Naqib Ahmad (b) (4) (b) (4)	13 Apr 2021 20:58:02
User entered 'CHEST PAIN (non-cardiac)' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	13 Apr 2021 20:58:02
User opened query 'Please specify type of chest pain e.g. cardiac, muscular. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 16:37:16
DataPoint Un-verified.		31 Mar 2021 16:34:51
DataPoint Verified.		31 Mar 2021 15:16:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 22:05:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 22:05:19
Data point term sent to Coder	System	30 Mar 2021 22:04:25

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Chest Pain'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:30
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:32
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:34
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:37
User entered '06 Oct 2020'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:39
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:41
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:43
User entered '09 Oct 2020'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:45
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:46
User entered 'Grade 4 (Grade 4)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:48
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:50
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:53
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:55
User entered 'I'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:57
User entered '06 Oct 2020'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:16:58
User entered '09 Oct 2020'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:02
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:03
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:05
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:07
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:11
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:14
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:19
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:21
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 22:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 22:04:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 22:03:48
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:17:25
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User closed query 'Please clarify if this should be yes as received aspirin in the ER. Source has yes. ' (Site from CRA).		23 Apr 2021 13:21:23
User closed query 'PV Query: Please consider updating the indication for the Aspirin administered on 06 Oct 2020. It is currently reported as Chest pain, cardiac and event term was updated to chest pain (non-cardiac).' (Site from Safety).		23 Apr 2021 13:05:18
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
	(b) (4)	
Query 'PV Query: Please consider updating the indication for the Aspirin administered on 06 Oct 2020. It is currently reported as Chest pain, cardiac and event term was updated to chest pain (non-cardiac).' answered with 'confirmed updated' (Site from Safety).	Jennifer Gaston (b) (4)	22 Apr 2021 20:46:42
	(b) (4)	
Query 'Please clarify if this should be yes as received aspirin in the ER. Source has yes. ' answered with 'confirmed yes' (Site from CRA).	Jennifer Gaston (b) (4)	22 Apr 2021 20:34:23
	(b) (4)	
User opened query 'PV Query: Please consider updating the indication for the Aspirin administered on 06 Oct 2020. It is currently reported as Chest pain, cardiac and event term was updated to chest pain (non-cardiac).' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:45:35
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:08:30
User entered '1' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	13 Apr 2021 20:57:40
	(b) (4)	
User opened query 'Please clarify if this should be yes as received aspirin in the ER. Source has yes. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:18:21
DataPoint Un-verified.		31 Mar 2021 15:17:35
DataPoint Verified.		31 Mar 2021 15:17:27
User entered '0'	Jennifer Gaston (b) (4)	30 Mar 2021 22:03:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:18:23
User entered 'l'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:18:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:18:28
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:19:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Mar 2021 22:05:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Mar 2021 22:05:55
User entered 'SUBJECT WAS AT A SURGERY CENTER ON 10/6/20 FOR LEFT ARTHROPLASTY. FOLLOWING SURGERY HER HEART RATE DROPPED TO 30 AND SHE WAS TAKEN BY AMBULANCE TO ER. SHE WAS LATER ADMITTED DUE TO CARDIAC HISTORY FOR FULL WORK UP AND EVALUATION. SHE WAS DISCHARGED HOME ON 10/9/20. MEDICAL RECORDS PENDING.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:05:55
MEDICAL RECORDS RECEIVED AND REVIEWED. SUBJECT HAD ROTATOR CUFF REPAIR SURGERY. IN POST OP- SUBJECT DEVELOPED BRADYCARDIA and reported chest pain, she WAS TRANSFERRED TO THE HOSPITAL. UPON ADMISSION, THE SUBJECT UNDERWENT EKG, CHEST CT WITH CONTRAST, A CARDIAC CATHETERIZATION AND A CHEST X-RAY. SUBJECT WAS DISCHARGED WITH INSTRUCTION TO FOLLOW UP.		
CARDIAC CATHETERIZATION- NO STENOSIS EKG- NORMAL, SINUS RHYTHM WITH SINUS ARRHYTHMIA INCOMPLETE RBBB (NONSPECIFIC EKG CHANGES) TROPONINS ARE NEGATIVE CT CHEST NEGATIVE FOR PE.' reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Mar 2021 22:03:48
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered 'I'	System	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered 'I'	System	30 Mar 2021 22:03:48

US3182227

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:36:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '0'	System	30 Mar 2021 22:03:48

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:36:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:01
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:01

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
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) (b) (4)	13 Aug 2020 18:33:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:33:26
Data point term sent to Coder	System	13 Aug 2020 18:31:46
User entered 'Aspirin'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Heart health'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	31 Mar 2021 11:55:29
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	30 Mar 2021 22:19:32
User signature succeeded.	(b) (4)	
	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '81'	Cassie Uminski (b) (4)	13 Aug 2020 18:31:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:42:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:31:26
User entered 'un UNK 1998'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '804 (804)'	System	13 Aug 2020 18:31:26

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:33:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:33:27
Data point term sent to Coder	System	13 Aug 2020 18:32:46
User entered 'Levothyroxine'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Hypothyroidism'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '25'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User closed query 'Per DM CLR: Please review the dose/unit of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:19:04
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:00:08
Query 'Per DM CLR: Please review the dose/unit of this medication as this is not the standard dose. Reconcile and update as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:02:21
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:01:56
User entered 'ug (ug)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 16:01:56
User opened query 'Per DM CLR: Please review the dose/unit of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 08:39:26
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:42:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:31:55
User entered 'un UNK 2013'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '804 (804)'	System	13 Aug 2020 18:31:55

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:33:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:33:27
Data point term sent to Coder	System	13 Aug 2020 18:32:47
User entered 'Lisinopril'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Hypertension'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '10'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:42:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:32:18
User entered 'un UNK 1998'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:00:31
DataPoint Un-verified.	Cassie Uminski (b) (4)	29 Oct 2020 16:02:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	29 Oct 2020 16:02:47
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:00:33
DataPoint Un-verified.	Cassie Uminski (b) (4)	29 Oct 2020 16:02:47
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 16:02:47
DataPoint Verified.	(b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User entered '1'	System	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User entered '1'	System	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:06
User entered '804 (804)'	System	13 Aug 2020 18:32:18

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:35:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:35:21
Data point term sent to Coder	System	13 Aug 2020 18:33:48
User entered 'Vitamin D'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Health maintenance'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '2000'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'IU (IU)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:42:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:33:32
User entered 'un UNK 2015'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '804 (804)'	System	13 Aug 2020 18:33:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:35:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:35:21
Data point term sent to Coder	System	13 Aug 2020 18:34:49
User entered 'Lipitor'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'High Cholesterol'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '10'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		13 Aug 2020 23:42:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:33:52
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered '0'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:29:40
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '1'	System	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '804 (804)'	System	13 Aug 2020 18:33:52

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
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) (b) (4)	23 Apr 2021 00:13:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 00:13:11
Data point term sent to Coder	System	22 Apr 2021 20:35:41
Coding entries removed.	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:34:53
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 13:30:45
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) (b) (4)	17 Mar 2021 20:36:48
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 20:36:48
Data point term sent to Coder	System	17 Mar 2021 20:21:20
Coding entries removed.	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:20:37
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

Name of Medication

Audit	User	Time (GMT)
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) (b) (4)	28 Feb 2021 18:59:27
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 Feb 2021 18:59:27
Data point term sent to Coder	System	28 Feb 2021 18:58:21
User entered 'Aspirin'	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:30:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.	(b) (4)	23 Apr 2021 13:28:13
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:06
DataPoint Un-verified.	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 20:34:53
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	22 Apr 2021 20:34:53
	(b) (4)	
User entered 'CHEST PAIN, Non CARDIAC.'	Jennifer Gaston (b) (4)	22 Apr 2021 20:34:53
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 13:30:50
	(b) (4)	
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4)	22 Mar 2021 08:25:50
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'corrected.' (Site from DM).	Naqib Ahmad (b) (4)	17 Mar 2021 20:20:46
	(b) (4)	
Signature has been broken.	Naqib Ahmad (b) (4)	17 Mar 2021 20:20:37
	(b) (4)	
User entered 'CHEST PAIN, cardiac.' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 20:20:37
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:56:02
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Chest Pain'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:00
User closed query 'Please clarify as source states from medical records. This is the dose that was given in the ER. ' (Site from CRA).		30 Mar 2021 13:30:57
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
	(b) (4)	
Query 'Please clarify as source states from medical records. This is the dose that was given in the ER. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	26 Mar 2021 17:05:37
	(b) (4)	
Signature has been broken.	Cassie Uminski (b) (4)	26 Mar 2021 17:05:22
	(b) (4)	
User entered 'Unknown' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 17:05:22
	(b) (4)	
User opened query 'Please clarify as source states from medical records. This is the dose that was given in the ER. ' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:38:51
User closed query 'How do you know the dose? ' (Site from CRA).		26 Mar 2021 14:38:51
Query 'How do you know the dose? ' answered with 'Per subject report' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 13:56:58
	(b) (4)	
User opened query 'How do you know the dose? ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 16:45:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered '81'	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:02
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 17:05:22
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Cassie Uminski (b) (4)	26 Mar 2021 17:05:22
Data Entry Error	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'mg (mg)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:05
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 17:05:22
	(b) (4)	
User entered 'Unknown' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 17:05:22
	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:10
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'once (ONCE)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Oral (ORAL)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '6 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:23
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:57:32
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '6 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
DataPoint Verified.		30 Mar 2021 13:31:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
User entered empty.	System	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
User entered empty.	System	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:15
User entered empty.	System	28 Feb 2021 18:57:32

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:31:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Feb 2021 19:00:27
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 Feb 2021 19:00:27
Data point term sent to Coder	System	28 Feb 2021 18:59:22
User entered 'IV fluids'	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:31:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:31:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Dehydration'	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:31:58
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
	(b) (4)	
Signature has been broken.	Cassie Uminski (b) (4)	26 Mar 2021 17:19:53
	(b) (4)	
User entered 'unknown' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 17:19:53
	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'I'	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Other (OTHER)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:03
User closed query 'Please clarify as I only see IV fluids not the amount. ' (Site from CRA).		30 Mar 2021 13:31:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
Query 'Please clarify as I only see IV fluids not the amount. ' answered with 'Updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Cassie Uminski (b) (4)	26 Mar 2021 17:20:12
	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 17:19:53
	(b) (4)	
User entered 'Unknown' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 17:19:53
	(b) (4)	
User opened query 'Please clarify as I only see IV fluids not the amount. ' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:39:39
User closed query 'How do you know how much was given? ' (Site from CRA).		26 Mar 2021 14:39:39
Query 'How do you know how much was given? ' answered with 'Per medical records' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 13:57:39
	(b) (4)	
User opened query 'How do you know how much was given? ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 16:48:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Liter'	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:06
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'once (ONCE)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:09
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:11
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '24 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:23
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '24 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
DataPoint Verified.		30 Mar 2021 13:32:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	28 Feb 2021 18:59:15
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
User entered empty.	System	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
User entered empty.	System	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:44:19
User entered empty.	System	28 Feb 2021 18:59:15

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:49:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:49:32
Data point term sent to Coder	System	30 Mar 2021 22:18:34
Coding entries removed.	Jennifer Gaston (b) (4) (b) (4)	30 Mar 2021 22:18:08
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 13:33:21
User signature succeeded.	Mary Beth Manning (b) (4)	18 Mar 2021 15:37:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 06:15:31
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 Mar 2021 06:15:31
Data point term sent to Coder	System	17 Mar 2021 20:19:18
User entered 'Oxycodone'	Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:19
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:04:49
User closed query 'Should this be shoulder arthroplasty instead of rotator cuff repair? ' (Site from CRA).		31 Mar 2021 16:04:44
User signature succeeded.	Mary Beth Manning	31 Mar 2021 11:55:29
	(b) (4)	
Query 'Should this be shoulder arthroplasty instead of rotator cuff repair? ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4)	30 Mar 2021 22:18:15
	(b) (4)	
Signature has been broken.	Jennifer Gaston (b) (4)	30 Mar 2021 22:18:08
	(b) (4)	
User entered 'PAIN SECONDARY TO LEFT Arthroplasty' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	30 Mar 2021 22:18:08
	(b) (4)	
User opened query 'Should this be shoulder arthroplasty instead of rotator cuff repair? ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 13:33:15
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered 'Pain secondary to left rotator cuff repair.'	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:21
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:24
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 20:18:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 20:18:46
User entered 'unknown' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 20:18:21
User entered empty.	System	17 Mar 2021 20:18:21
	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:21
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:27
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 20:18:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 20:18:46
User entered 'Other (OTHER)' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 20:18:21
User entered empty.	System	17 Mar 2021 20:18:21
	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:29
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered 'unknown.' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:46
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:21
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:32
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 20:18:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 20:18:55
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Mar 2021 20:18:21
User entered empty.	System	17 Mar 2021 20:18:21
	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:21
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:41
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:43
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Oral (ORAL)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:46
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:33:50
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 17:22:04
	(b) (4)	
User entered 'un Oct 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 17:22:04
	(b) (4)	
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:21
	(b) (4)	

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User closed query 'Should this be Oct2020? We know it started after the surgery on 06Oct2020. ' (Site from CRA).		30 Mar 2021 13:34:01
DataPoint Verified.		30 Mar 2021 13:33:58
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
	(b) (4)	
Query 'Should this be Oct2020? We know it started after the surgery on 06Oct2020. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	26 Mar 2021 17:22:19
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 17:22:04
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Cassie Uminski (b) (4)	26 Mar 2021 17:22:04
	(b) (4)	
User opened query 'Should this be Oct2020? We know it started after the surgery on 06Oct2020. ' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:40:29
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
	(b) (4)	
User entered '1'	Naqib Ahmad (b) (4)	17 Mar 2021 20:18:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:34:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		26 Apr 2021 13:55:46
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Confirmed correct as is, as the day is unknown' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 19:37:51
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:51:57
User closed query 'Should this be UnkOct2020 since the actual stop date is not known?' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 13:34:10
DataPoint Verified.		30 Mar 2021 13:34:08
User signature succeeded.	Mary Beth Manning (b) (4)	27 Mar 2021 16:57:01
Query 'Should this be UnkOct2020 since the actual stop date is not known?' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 17:22:32
User entered 'un Oct 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 17:22:04
User opened query 'Should this be UnkOct2020 since the actual stop date is not known?' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:41:02
User closed query 'How do you know this is the stop date? Page 68 of 87 written on 24Oct2020 says stopped 2 or 3 days ago.' (Site from CRA).		26 Mar 2021 14:41:02
Query 'How do you know this is the stop date? Page 68 of 87 written on 24Oct2020 says stopped 2 or 3 days ago.' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:59:43
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:59:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 13:59:39
User opened query 'How do you know this is the stop date? Page 68 of 87 written on 24Oct2020 says stopped 2 or 3 days ago. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 16:57:56
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '24 Oct 2020'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		30 Mar 2021 13:34:13
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'No (N)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	17 Mar 2021 20:18:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:36:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered empty.	System	17 Mar 2021 20:18:21

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:36:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		18 Mar 2021 16:40:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	28 Feb 2021 19:00:50
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Feb 2021 03:16:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		19 Mar 2021 15:08:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '24 Oct 2020'	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 19:01:18
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		19 Mar 2021 15:08:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'EKG'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:01:18

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		19 Mar 2021 15:08:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	28 Feb 2021 19:02:04
	(b) (4)	
User entered 'Adverse Event (AE)'	Jennifer Gaston (b) (4)	28 Feb 2021 19:01:18
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		19 Mar 2021 15:08:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 19:01:18
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:16
DataPoint Verified.		19 Mar 2021 15:13:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '24 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:01:54

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:16
DataPoint Verified.		19 Mar 2021 15:13:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'EKG'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:01:54

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:16
DataPoint Verified.		19 Mar 2021 15:13:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:01:54

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:16
DataPoint Verified.		19 Mar 2021 15:13:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 19:01:54
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:19
DataPoint Verified.		22 Apr 2021 20:56:13
User closed query 'Per cath H&P was done at 16:31 on 07Oct2020 but I don't see anywhere in the records the date the cath was completed. ' (Site from CRA).		22 Apr 2021 20:56:12
Query 'Per cath H&P was done at 16:31 on 07Oct2020 but I don't see anywhere in the records the date the cath was completed. ' answered with 'Exact date is unknown as no report of catherization is not available. Subject WD consent, thus further records unavailable ' (Site from CRA).	Jennifer Gaston (b) (4)	22 Apr 2021 20:30:22
User opened query 'Per cath H&P was done at 16:31 on 07Oct2020 but I don't see anywhere in the records the date the cath was completed. ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 13:26:41
User closed query 'How do we know the date? ' (Site from CRA).		30 Mar 2021 13:26:41
Query 'How do we know the date? ' answered with 'Per medical records' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 15:17:26
User opened query 'How do we know the date? ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:40:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '7 Oct 2020'	Jennifer Gaston (b) (4)	28 Feb 2021 19:02:40

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:19
DataPoint Verified.		30 Mar 2021 13:26:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Cardiac Catherization'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:02:40

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:19
DataPoint Verified.		30 Mar 2021 13:26:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:02:40

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:19
DataPoint Verified.		30 Mar 2021 13:26:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:02:40

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:24
DataPoint Verified.		19 Mar 2021 14:12:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '6 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:03:21

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:24
DataPoint Verified.		19 Mar 2021 14:12:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Chest CT with Contrast'	Jennifer Gaston (b) (4)	28 Feb 2021 19:03:21
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:24
DataPoint Verified.		19 Mar 2021 14:12:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:03:21

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:24
DataPoint Verified.		19 Mar 2021 14:12:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 19:03:21
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:27
DataPoint Verified.		19 Mar 2021 14:40:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '8 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:03:51

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:27
DataPoint Verified.		19 Mar 2021 14:40:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Chest X-Ray'	Jennifer Gaston (b) (4)	28 Feb 2021 19:03:51
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:27
DataPoint Verified.		19 Mar 2021 14:40:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:03:51

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:27
DataPoint Verified.		19 Mar 2021 14:40:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 19:03:51
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:32
DataPoint Verified.		19 Mar 2021 14:42:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '24 Oct 2020'	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 19:04:16
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:32
DataPoint Verified.		19 Mar 2021 14:42:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Chest X-Ray'	Jennifer Gaston (b) (4)	28 Feb 2021 19:04:16
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:32
DataPoint Verified.		19 Mar 2021 14:42:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4)	28 Feb 2021 19:04:16
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:32
DataPoint Verified.		19 Mar 2021 14:42:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:04:16

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:35
DataPoint Verified.		19 Mar 2021 14:46:09
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '24 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:06:55

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:35
DataPoint Verified.		19 Mar 2021 14:46:09
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'CT of Brain'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:06:55

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:35
DataPoint Verified.		19 Mar 2021 14:46:09
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:06:55

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:35
DataPoint Verified.		19 Mar 2021 14:46:09
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 19:06:55
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:39
DataPoint Verified.		19 Mar 2021 14:47:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '24 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:07:18

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:39
DataPoint Verified.		19 Mar 2021 14:47:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Chest CT with Contrast'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 19:07:18

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:39
DataPoint Verified.		19 Mar 2021 14:47:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4)	28 Feb 2021 19:07:18
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:39
DataPoint Verified.		19 Mar 2021 14:47:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	28 Feb 2021 19:07:18
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:42
DataPoint Verified.		30 Mar 2021 13:27:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '06 Oct 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:33:31

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:42
DataPoint Verified.		30 Mar 2021 13:28:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:50
User closed query 'Should this be Left shoulder arthroplasty instead of rotator cuff repair? Noted on several hospital records. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:23:27
Query 'Should this be Left shoulder arthroplasty instead of rotator cuff repair? Noted on several hospital records. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:23:31
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:18:47
User entered 'LEFT shoulder arthroplasty' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:18:47
User opened query 'Should this be Left shoulder arthroplasty instead of rotator cuff repair? Noted on several hospital records. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:52:04
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
User entered 'Left Rotator Cuff Repair'	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:33:31

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:42
DataPoint Verified.		30 Mar 2021 13:28:23
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 20:33:31

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:42
DataPoint Verified.		30 Mar 2021 13:28:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered empty.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 20:33:31
	(b) (4)	

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:36:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:47
DataPoint Verified.		30 Mar 2021 13:28:45
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '6 Oct 2020'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:39:28

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:36:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:47
DataPoint Verified.		30 Mar 2021 13:28:47
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Bloodwork (Troponin)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:39:28

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:36:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:47
DataPoint Verified.		30 Mar 2021 13:28:51
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:39:28

US3182227

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:36:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:41:47
DataPoint Verified.		30 Mar 2021 13:28:54
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered empty.	(b) (4) Naqib Ahmad (b) (4) (b) (4)	17 Mar 2021 19:39:28

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:16

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:44
DataPoint Verified.		31 Mar 2021 16:40:39
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
User entered '02 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 16:56:19

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:16

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:44
DataPoint Verified.		31 Mar 2021 16:40:39
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
	(b) (4)	
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Cassie Uminski (b) (4)	26 Mar 2021 16:56:19
	(b) (4)	

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:16

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:44
DataPoint Verified.		31 Mar 2021 16:40:39
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
User entered 'Subject choice to withdrawal'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 16:56:19

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:16

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:44
DataPoint Verified.		31 Mar 2021 16:40:39
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 16:56:19

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:16

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:44
DataPoint Verified.		31 Mar 2021 16:40:39
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	26 Mar 2021 16:56:19
	(b) (4)	

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:16

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:44
DataPoint Verified.		31 Mar 2021 16:40:39
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	26 Mar 2021 16:56:19
	(b) (4)	

US3182227

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:36:16

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:44
DataPoint Verified.		31 Mar 2021 16:40:39
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:57:01
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	26 Mar 2021 16:56:19
	(b) (4)	

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:36:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
User entered '30/Oct/2020 13:06'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:36:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.	(b) (4)	18 Mar 2021 12:09:34
Un-reviewed for Safety.	(b) (4)	18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.	(b) (4)	30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4)	30 Oct 2020 17:07:07
	(b) (4)	

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:36:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:30:47
User entered '23/Nov/2020 20:25'	System	23 Nov 2020 20:25:28

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:36:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 20:25:28

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.	(b) (4)	18 Mar 2021 12:09:34
Un-reviewed for Safety.	(b) (4)	18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.	(b) (4)	30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4)	30 Oct 2020 17:07:07
	(b) (4)	

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:36:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:39:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
User entered '01/Mar/2021 11:49'	(b) (4) System	01 Mar 2021 16:49:14

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:36:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:39:13
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
User entered 'I'		01 Mar 2021 16:49:14

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

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Generated On: 09 Jun 2021 15:36:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:36:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
DataPoint Verified.		31 Mar 2021 16:39:16
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered '18/Mar/2021 12:09'	(b) (4) System	18 Mar 2021 12:09:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:36:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
DataPoint Verified.		31 Mar 2021 16:39:16
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:37:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:09:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:36:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:20
User entered '31/Mar/2021 11:10'	System	31 Mar 2021 15:10:52

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:36:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:20
User entered 'I'		31 Mar 2021 15:10:52

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:36:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
User entered '14/Apr/2021 12:23'	System	14 Apr 2021 16:23:37

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:36:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 16:23:37

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'USA-US075-2020-MRNA-1273-P301000004'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:38:50
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		14 Apr 2021 16:23:22
User signature succeeded.	Toby Briskin (b) (4)	02 Apr 2021 14:30:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:39:00
Signature has been broken.	System	31 Mar 2021 15:09:47
User entered 'Yes (Y)'	System	31 Mar 2021 15:09:47
User signature succeeded.	Mary Beth Manning (b) (4)	31 Mar 2021 11:55:29
Un-reviewed for Safety.	System	30 Mar 2021 22:01:21
DataPoint Un-verified.	System	30 Mar 2021 22:01:21
Signature has been broken.	System	30 Mar 2021 22:01:21
User entered 'No (N)'	System	30 Mar 2021 22:01:21
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Yes (Y)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

US3182227

Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'No (N)'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Toby'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:49
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Jennifer'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Mary Beth'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Briskin'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Un-verified.		08 Dec 2020 17:30:50
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered 'Gaston'	System	23 Nov 2020 20:25:28
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:55:12
Reviewed for Safety.		30 Oct 2020 13:06:44
User entered 'Manning'	System	30 Oct 2020 13:05:30

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '3619 Park East Drive, Suite 300'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '3169 Park East Dr. #300'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered 'Beachwood'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'Cleveland'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Form: Safety Report Form

Generated On: 09 Jun 2021 15:36:16

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.	(b) (4)	18 Mar 2021 12:09:34
Un-reviewed for Safety.	(b) (4)	18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.	(b) (4)	30 Oct 2020 17:55:12
User entered 'OH'	Amy Maroun (b) (4)	30 Oct 2020 17:07:07
	(b) (4)	

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:54
Un-reviewed for Safety.	System	14 Apr 2021 16:23:37
DataPoint Un-verified.	System	14 Apr 2021 16:23:37
Signature has been broken.	System	14 Apr 2021 16:23:37
User entered '44122'	System	14 Apr 2021 16:23:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 16:49:54
DataPoint Verified.		08 Dec 2020 17:30:47
Un-reviewed for Safety.	System	23 Nov 2020 20:25:28
DataPoint Un-verified.	System	23 Nov 2020 20:25:28
User entered empty.	System	23 Nov 2020 20:25:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered '44122'	Amy Maroun (b) (4) (b) (4)	30 Oct 2020 17:07:07

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
Reviewed for Safety.		18 Mar 2021 12:09:34
Un-reviewed for Safety.		18 Mar 2021 12:09:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:25:18
DataPoint Verified.		30 Oct 2020 17:55:12
User entered 'US'	System	30 Oct 2020 13:06:50

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Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User entered '7'	System	23 Apr 2021 13:06:28
User entered '6'	System	14 Apr 2021 16:23:37
User entered '5'	System	31 Mar 2021 15:10:52
User entered '4'	System	18 Mar 2021 12:09:50
User entered '3'	System	01 Mar 2021 16:49:14
User entered '2'	System	23 Nov 2020 20:25:28
User entered '1'	System	30 Oct 2020 13:06:50

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:36:16

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 15:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:30:03
User entered '23/Apr/2021 06:06'	System	23 Apr 2021 13:06:28

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Folder: SAE USA-US075-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:36:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:33
User signature succeeded.	Mary Beth Manning	23 Apr 2021 15:17:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:30:03
User entered 'I'		23 Apr 2021 13:06:28