

US3182151 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3182151

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

[Participant ID](#)

US3182151

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

US3182151

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3182151

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
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

US3182151

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	4 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

US3182151

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3182151

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Were any significant conditions reported?

Yes ☒

No ☐

US3182151

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Condition	SEASONAL ALLERGIES
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)	_____

US3182151

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Condition	BILATERAL MYOPIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3182151

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3182151

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3182151

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:43
Height (xxx.x)	170.9 cm
Weight (xxx.x)	101.9 kg
BMI (xxx.x)	34.88912 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)	

US3182151

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

US3182151

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Date of assessment (dd MMM yyyy) 04 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3182151

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	04 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3182151

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

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

US3182151

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:39:50

Generated On: 11 Aug 2021 22:09:01

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	

US3182151

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 100885

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 ☒

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Height	ND - Not Done
Weight	ND - Not Done

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

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)	04 AUG 2020
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:43
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

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)	04 AUG 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 13:30
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	51 mmHg
Diastolic Blood Pressure units	MMHG

US3182151

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

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.

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

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) 4 AUG 2020

What was the treatment time? (00:00-23:59) 12:55 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 12:55

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

US3182151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 AUG 2020

Collection time (00:00-23:59)

12:35 (24 HR)

Collection date and time (derived)

04 AUG 2020 12:35

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:13	04 AUG 2020 12:13
Nasopharyngeal Swab 2	No		

US3182151

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

97.6 °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

04 AUG 2020 13:22

PC Open Date & Time

04 AUG 2020 13:15

PC Close Date & Time

04 AUG 2020 15:45

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

98.2 °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	04 AUG 2020 20:09
PC Open Date & Time	04 AUG 2020 16:40
PC Close Date & Time	05 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 20:09

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	06 AUG 2020 20:15
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

07 AUG 2020 22:22

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 06:01

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

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

09 AUG 2020 20:05

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	10 AUG 2020 22:44
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

04 AUG 2020 13:23

PC Open Date & Time

04 AUG 2020 13:15

PC Close Date & Time

04 AUG 2020 15:45

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 20:09

PC Open Date & Time

04 AUG 2020 16:40

PC Close Date & Time

05 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

05 AUG 2020 20:10

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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

06 AUG 2020 20:15

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

07 AUG 2020 22:22

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 06:01

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 6
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	09 AUG 2020 20:06
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	10 AUG 2020 22:44
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 ☐

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 13:23
PC Open Date & Time	04 AUG 2020 13:15
PC Close Date & Time	04 AUG 2020 15:45

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 ☐

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 20:10
PC Open Date & Time	04 AUG 2020 16:40
PC Close Date & Time	05 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

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 ☒

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 20:11
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

52 of 1434

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:17
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 1434

EAB) (1725)

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 22:23
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 1434

EAB) (1725)

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 06:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

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 ☒

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:06
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 1434

EAB) (1725)

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 22:45
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:01

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

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3182151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

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

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

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)	01 SEP 2020
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 16:04
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	17:11 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 17:11
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3182151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	01 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 16:36 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 16:36

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

US3182151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 SEP 2020

Collection time (00:00-23:59)

16:15 (24 HR)

Collection date and time (derived)

01 SEP 2020 16:15

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:05	01 SEP 2020 16:05
Nasopharyngeal Swab 2	No		

US3182151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

01 SEP 2020 17:06

PC Open Date & Time

01 SEP 2020 16:56

PC Close Date & Time

01 SEP 2020 19:26

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 98.2 °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	02 SEP 2020 00:29
PC Open Date & Time	01 SEP 2020 20:21
PC Close Date & Time	02 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 21:04

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 19:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 21:44

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

01 SEP 2020 17:06

PC Open Date & Time

01 SEP 2020 16:56

PC Close Date & Time

01 SEP 2020 19:26

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

02 SEP 2020 00:29

PC Open Date & Time

01 SEP 2020 20:21

PC Close Date & Time

02 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

02 SEP 2020 21:05

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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

03 SEP 2020 21:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

04 SEP 2020 19:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

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

05 SEP 2020 19:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

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

06 SEP 2020 22:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

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

07 SEP 2020 21:44

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 ☐

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 17:07
PC Open Date & Time	01 SEP 2020 16:56
PC Close Date & Time	01 SEP 2020 19:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 ☐

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 00:29
PC Open Date & Time	01 SEP 2020 20:21
PC Close Date & Time	02 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

101 of 1434

EAB) (1725)

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 ☒

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:39
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

105 of 1434

EAB) (1725)

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:06
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

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 ☒

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:03
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

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

109 of 1434

EAB) (1725)

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

111 of 1434

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:44
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3182151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:34

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

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

US3182151

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

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

US3182151

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:04

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:14
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

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.

US3182151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

14:23 (24 HR)

Collection date and time (derived)

29 SEP 2020 14:23

US3182151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:09

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 OCT 2020 12:55:15

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 08:53:20

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 14:12:02

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 NOV 2020 09:05:37
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 21:50:12
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 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	17 NOV 2020 12:09:27
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 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	23 NOV 2020 20:22:07
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 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	27 NOV 2020 18:15:01
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 10:43:49
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 03:58:45

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 12:49:20

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 10:33:40

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 15:51:36
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 11:55:59
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 12:02:30

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 21:06:41
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 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	04 FEB 2021 07:23:40
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 10:55:26

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 06:22:10
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 12:05:38

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3182151

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:09:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 12:05:47

US3182151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182151

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:33:54

Generated On: 11 Aug 2021 22:09:01

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3182151

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:09:01

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"/>

US3182151

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:09:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3182151

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

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

Visit date (dd MMM yyyy)	04 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3182151

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Date of updated informed consent (<i>dd MMM yyyy</i>)	04 FEB 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>)	04 FEB 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	

US3182151

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00-23:59)	14:59 (24 HR)
Collection date and time (derived)	04 FEB 2021 14:59

US3182151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00 - 23:59)	14:45
Collection Date and Time (derived)	04 FEB 2021 14:45

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Visit Date	29 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	True

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	29 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3182151

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

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

Yes ☒

No ☐

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

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Name of Medication MULTIVITAMIN (UNKNOWN)

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

171 of 1434

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

	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 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

173 of 1434

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

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

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Name of Medication PRENATAL VITAMIN (BRAND UNKNOWN)

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

175 of 1434

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

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

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Name of Medication B12 VITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 5000

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)

177 of 1434

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Name of Medication FOLIC ACID

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

179 of 1434

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 650

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)

181 of 1434

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

	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)	06 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	06 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication JOINT ACHES

Dose per administration 650

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)

183 of 1434

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

	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)	10 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 AUG 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3182151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:23:06

Generated On: 11 Aug 2021 22:09:01

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Apr 2021 12:19:00

Generated On: 11 Aug 2021 22:09:01

Date of study discontinuation/completion (dd MMM yyyy) 24 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 checked="" type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

If reason for discontinuation is Death, main cause of death

Adverse event	<input 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"/>

Audit

US3182151 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182151

Form: Participant Creation

Generated On: 11 Aug 2021 22:09:01

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Aug 2020 21:15:25
User entered 'US3182151'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:04:29

US3182151

Form: Participant Creation

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:46:34
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:12

US3182151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:46:43
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:04:30

US3182151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:46:45
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:12

US3182151

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'SCRN'	System	04 Aug 2020 16:57:12

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:02
User entered (b) (6) 1979'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:04:31

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:04
User entered '41'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'YEARS'	System	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '41'	System	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:09
User entered 'Female (F)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

US3182151

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:01

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:05:40

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US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:36
User entered '4 Aug 2020'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'Aug 2020'	System	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '2020'	System	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:36
User entered 'Amendment 1 (1)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:36
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:36
User entered empty.	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:36
User entered empty.	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:36
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:24

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:47:36
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:04:30

US3182151

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'I'	System	04 Aug 2020 16:57:29

US3182151

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 22:52:57
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:29

US3182151

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:09:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:48:00
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:06

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:48:30
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:12:21
Data point term sent to Coder	System	11 Aug 2020 19:10:58
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:48:30
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:48:30
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:48:30
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:48:30
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:48:30
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'Jan 2010'	System	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '2010'	System	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered empty.	System	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered empty.	System	11 Aug 2020 19:10:16

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:56:10
User closed query 'Per DM CLR: Please update the condition to include the laterality of Myopia (e.g. Left, Right, Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		14 Sep 2020 04:58:39
User coded data point as SOC: Eye disorders, HLGT: Coder Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\23.0.	(b) (4) (b) (4)	09 Sep 2020 20:24:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:24:46
Data point term sent to Coder	System	09 Sep 2020 20:24:12
Query 'Per DM CLR: Please update the condition to include the laterality of Myopia (e.g. Left, Right, Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:24:10
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:49
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:49
User entered 'Bilateral MYOPIA' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:49
User opened query 'Per DM CLR: Please update the condition to include the laterality of Myopia (e.g. Left, Right, Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 07:23:33
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 13:50:34

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 19:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 19:12:21
Data point term sent to Coder	System	11 Aug 2020 19:10:59
User entered 'Myopia'	Cassie Uminski (b) (4)	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:50:34
User entered 'un UNK 2017'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:50:34
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:50:34
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:50:34
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:50:34
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'Jan 2017'	System	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '2017'	System	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered empty.	System	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered empty.	System	11 Aug 2020 19:10:23

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:52:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:12:21
Data point term sent to Coder	System	11 Aug 2020 19:10:59
User entered 'Gastric Bypass'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:52:02
User entered 'un UNK 2009'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:52:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:52:02
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:52:02
User entered 'un UNK 2009'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:52:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'Jan 2009'	System	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '2009'	System	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'Jan 2009'	System	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '2009'	System	11 Aug 2020 19:10:43

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:53:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:12:21
Data point term sent to Coder	System	11 Aug 2020 19:12:00
User entered 'Obesity'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:53:57
User entered 'un UNK 1999'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:53:57
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:53:57
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:53:57
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:53:57
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'Jan 1999'	System	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '1999'	System	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered empty.	System	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered empty.	System	11 Aug 2020 19:11:19

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered '11:43'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered '04 Aug 2020 11:43'	System	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered '170.9' cm	Cassie Uminski (b) (4)	11 Aug 2020 19:06:09
DataPoint set to visible.	(b) (4) System	04 Aug 2020 16:57:29

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered '101.9' kg	Cassie Uminski (b) (4)	11 Aug 2020 19:06:09
DataPoint set to visible.	(b) (4) System	04 Aug 2020 16:57:29

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
Amendment Manager: User entered '34.88912'	System	16 Sep 2020 23:42:31
User entered '34.9'	System	11 Aug 2020 19:06:09
DataPoint set to visible.	System	04 Aug 2020 16:57:29

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'kg/m2'	System	11 Aug 2020 19:06:09
DataPoint set to visible.	System	04 Aug 2020 16:57:29

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 12:07:54
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).		14 Sep 2020 04:58:54
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)	09 Sep 2020 20:23:25
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:21
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:21
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 04:58:42
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'bpm'	System	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'breaths/min'	System	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'mmHg'	System	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:59:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered 'mmHg'	System	11 Aug 2020 19:06:09

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:51:05

US3182151

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:51:05

US3182151

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:02:10
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:05

US3182151

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:39:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 20:38:21
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:02:10
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:05

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:01

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:10
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:17

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:18
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:18
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:18
User entered 'Urine (URINE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:18
User entered 'Negative (NEGATIVE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
Query 'Query Text: Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).		19 Mar 2021 20:45:39
User opened query 'Query Text: Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).		19 Mar 2021 17:52:10
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:18
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:18
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:04:18
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User entered empty.	System	11 Aug 2020 19:07:29

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

[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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

[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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

[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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	(b) (4)	11 Aug 2020 19:09:41
User entered '1' reason for change: Data Entry Error	Cassie Uminski (b) (4)	11 Aug 2020 19:09:41
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	(b) (4)	11 Aug 2020 19:09:30
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

[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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
User entered '0'	(b) (4)	11 Aug 2020 19:09:30
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182151

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:51:05
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:45
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:30

US3182151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:58
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:04

US3182151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:58
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:04

US3182151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:05:58
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:09:04

US3182151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'VISIT1'	System	11 Aug 2020 19:09:04

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:06:14
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:39:39

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 22:57:28
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:57:53
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:57:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 16:39:39
User entered '100885' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:39:39

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:06:16
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 16:39:39

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:06:18
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:54

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:06:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:54

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:06:21
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:54

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:06:23
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:54

US3182151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:06:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:54

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:14
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:14
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered '11:43'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '04 Aug 2020 11:43'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered '98.2' F	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered '69'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'bpm'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered '14'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'breaths/min'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered '104'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:33
User entered '69'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:14
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:00:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
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).		17 Aug 2020 23:36:18
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).		11 Aug 2020 19:07:02
User entered '13:30'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '04 Aug 2020 13:30'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered '97.6' F	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered '70'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'bpm'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered '14'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'breaths/min'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered '100'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Oct 2020 14:29:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:31:23
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:42:31
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:07:10
User entered '51'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	11 Aug 2020 19:07:02

US3182151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:16:35
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:11

US3182151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:16:35
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:11

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 22:55:24
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and V1D1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, when Screening and V1D1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' answered with 'removed per query' (Site from DM).	(b) (4)	06 Oct 2020 22:11:25
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	03 Oct 2020 21:50:22
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4)	03 Oct 2020 21:49:49
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and V1D1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, when Screening and V1D1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test and FSH sample data should be removed from this page. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 15:01:32
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and V1D1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test and FSH sample data should be removed from this page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 15:01:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 17:41:03
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 1434

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 22:55:24
DataPoint Un-verified.	Amy Maroun (b) (4)	03 Oct 2020 21:49:49
User entered empty; reason for change Data Entry Error	(b) (4) Amy Maroun (b) (4)	03 Oct 2020 21:49:49
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:16:40
User entered '04 Aug 2020'	Cassie Uminski (b) (4)	11 Aug 2020 19:07:39

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 22:55:24
DataPoint Un-verified.	Amy Maroun (b) (4)	03 Oct 2020 21:49:49
User entered empty; reason for change Data Entry Error	(b) (4) Amy Maroun (b) (4)	03 Oct 2020 21:49:49
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:16:40
User entered 'Urine (URINE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:39

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 22:55:24
DataPoint Un-verified.	Amy Maroun (b) (4)	03 Oct 2020 21:49:49
User entered empty; reason for change Data Entry Error	(b) (4) Amy Maroun (b) (4)	03 Oct 2020 21:49:49
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:16:40
User entered 'Negative (NEGATIVE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:39

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 22:55:24
DataPoint Un-verified.	Amy Maroun (b) (4)	03 Oct 2020 21:49:49
User entered empty; reason for change Data Entry Error	(b) (4) Amy Maroun (b) (4)	03 Oct 2020 21:49:49
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:16:40
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 19:07:39

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:16:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:39

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:16:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:07:39

US3182151

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered empty.	System	11 Aug 2020 19:07:39

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:17:54
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:17:54
User entered empty.	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:17:54
User entered empty.	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:17:54
User entered '4 Aug 2020'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:17:54
User entered '12:55'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '4 Aug 2020 12:55'	System	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:17:54
User entered 'Left Arm (LEFT ARM)'	Amy Maroun (b) (4) (b) (4)	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
DataPoint Verified.		19 Aug 2020 14:17:54
User entered 'ONCE'	System	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 16:57:52

US3182151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:01
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:42

US3182151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:01
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:42

US3182151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:01
User entered '12:35'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:42

US3182151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '04 Aug 2020 12:35'	System	11 Aug 2020 19:08:42

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:09:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:10
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:10
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:10
User entered '12:13'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '04 Aug 2020 12:13'	System	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	11 Aug 2020 19:08:25
	(b) (4)	

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:10
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:10
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered empty.	System	11 Aug 2020 19:08:25

US3182151

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:18:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:08:49

US3182151

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '1'	System	11 Aug 2020 19:08:49

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:21:47', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8ff8d142-7c0f-4f0d-bbff-71e52c5998f5'	System	04 Aug 2020 17:22:57
User entered 'Yes (Y)'	System	04 Aug 2020 17:22:57

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:22:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8ff8d142-7c0f-4f0d-bbff-71e52c5998f5'	System	04 Aug 2020 17:22:57
User entered '97.6'	System	04 Aug 2020 17:22:57

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:22:49', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8ff8d142-7c0f-4f0d-bbff-71e52c5998f5'	System	04 Aug 2020 17:22:57
User entered 'No (N)'	System	04 Aug 2020 17:22:57

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:22:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8ff8d142-7c0f-4f0d-bbff-71e52c5998f5'	System	04 Aug 2020 17:22:57
User entered '04 Aug 2020 13:22'	System	04 Aug 2020 17:22:57

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 13:15'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 15:45'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:08:46', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b60b0c32-71fb-47ae-bc6a-ecdffdb44f82'	System	05 Aug 2020 00:09:05
User entered 'Yes (Y)'	System	05 Aug 2020 00:09:05

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:08:51', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b60b0c32-71fb-47ae-bc6a-ecdffdb44f82' User entered '98.2'	System	05 Aug 2020 00:09:05
	System	05 Aug 2020 00:09:05

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:08:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b60b0c32-71fb-47ae-bc6a-ecdffdb44f82'	System	05 Aug 2020 00:09:05
User entered 'No (N)'	System	05 Aug 2020 00:09:05

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b60b0c32-71fb-47ae-bc6a-ecdffdb44f82'	System	05 Aug 2020 00:09:05
User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:09:05

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 16:40'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 2'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:09:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6487b71a-1d75-4bee-9f34-d38a8abdb583' User entered 'Yes (Y)'	System	06 Aug 2020 00:09:59
	System	06 Aug 2020 00:09:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:09:50', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6487b71a-1d75-4bee-9f34-d38a8abdb583' User entered '98.0'	System	06 Aug 2020 00:09:59
	System	06 Aug 2020 00:09:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:09:54', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6487b71a-1d75-4bee-9f34-d38a8abdb583'	System	06 Aug 2020 00:09:59
User entered 'No (N)'	System	06 Aug 2020 00:09:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:09:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6487b71a-1d75-4bee-9f34-d38a8abdb583' User entered '05 Aug 2020 20:09'	System	06 Aug 2020 00:09:59
	System	06 Aug 2020 00:09:59

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 3'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:13:33', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6e62aad1-5935-4600-9208-35777e69401c' User entered 'Yes (Y)'	System	07 Aug 2020 00:15:17
	System	07 Aug 2020 00:15:17

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:13:40', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6e62aad1-5935-4600-9208-35777e69401c' User entered '97.7'	System	07 Aug 2020 00:15:17
	System	07 Aug 2020 00:15:17

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:14:56', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6e62aad1-5935-4600-9208-35777e69401c' User entered 'Yes (Y)'	System	07 Aug 2020 00:15:17
	System	07 Aug 2020 00:15:17

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	31 Oct 2020 14:26:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Maroun (b) (4)	29 Oct 2020 12:27:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6e62aad1-5935-4600-9208-35777e69401c'	(b) (4)	
User entered '1'	System	07 Aug 2020 00:15:17
	System	07 Aug 2020 00:15:17
	System	07 Aug 2020 00:15:17

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6e62aad1-5935-4600-9208-35777e69401c' User entered '0'	System	07 Aug 2020 00:15:17
	System	07 Aug 2020 00:15:17

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:14', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6e62aad1-5935-4600-9208-35777e69401c' User entered '06 Aug 2020 20:15'	System	07 Aug 2020 00:15:17
	System	07 Aug 2020 00:15:17

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 4'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:11', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '23bfe43c-32ba-4d3c-9cc8-9f2604961151' User entered 'Yes (Y)'	System	08 Aug 2020 02:22:25
	System	08 Aug 2020 02:22:25

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '23bfe43c-32ba-4d3c-9cc8-9f2604961151' User entered '97.6'	System	08 Aug 2020 02:22:25
	System	08 Aug 2020 02:22:25

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:20', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '23bfe43c-32ba-4d3c-9cc8-9f2604961151'	System	08 Aug 2020 02:22:25
User entered 'No (N)'	System	08 Aug 2020 02:22:25

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:22', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '23bfe43c-32ba-4d3c-9cc8-9f2604961151' User entered '07 Aug 2020 22:22'	System	08 Aug 2020 02:22:25
	System	08 Aug 2020 02:22:25

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 5'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:18', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0b510044-d8f2-4c4e-aa05-519020c8dc41' User entered 'Yes (Y)'	System	09 Aug 2020 10:01:33
	System	09 Aug 2020 10:01:33

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:22', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0b510044-d8f2-4c4e-aa05-519020c8dc41' User entered '98.7'	System	09 Aug 2020 10:01:33
	System	09 Aug 2020 10:01:33

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:27', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0b510044-d8f2-4c4e-aa05-519020c8dc41' User entered 'No (N)'	System	09 Aug 2020 10:01:33
	System	09 Aug 2020 10:01:33

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:30', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0b510044-d8f2-4c4e-aa05-519020c8dc41' User entered '09 Aug 2020 06:01'	System	09 Aug 2020 10:01:33
	System	09 Aug 2020 10:01:33

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 6'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:05:29', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2e0536d9-286f-4b78-9ed5-8ba5a4d7a569' User entered 'Yes (Y)'	System	10 Aug 2020 00:05:44
	System	10 Aug 2020 00:05:44

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:05:33', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2e0536d9-286f-4b78-9ed5-8ba5a4d7a569' User entered '98.7'	System	10 Aug 2020 00:05:44
	System	10 Aug 2020 00:05:44

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:05:35', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2e0536d9-286f-4b78-9ed5-8ba5a4d7a569'	System	10 Aug 2020 00:05:44
User entered 'No (N)'	System	10 Aug 2020 00:05:44

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:05:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2e0536d9-286f-4b78-9ed5-8ba5a4d7a569' User entered '09 Aug 2020 20:05'	System	10 Aug 2020 00:05:44
	System	10 Aug 2020 00:05:44

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 7'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:43:52', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a699f82e-0ab0-4faa-ba22-1240eb24f34a' User entered 'Yes (Y)'	System	11 Aug 2020 02:44:13
	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:43:56', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a699f82e-0ab0-4faa-ba22-1240eb24f34a' User entered '98.8'	System	11 Aug 2020 02:44:13
	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a699f82e-0ab0-4faa-ba22-1240eb24f34a' User entered 'Yes (Y)'	System	11 Aug 2020 02:44:13
	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	31 Oct 2020 14:29:14
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Maroun (b) (4)	29 Oct 2020 12:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a699f82e-0ab0-4faa-ba22-1240eb24f34a'	(b) (4)	
User entered '1'	System	11 Aug 2020 02:44:13
	System	11 Aug 2020 02:44:13
	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a699f82e-0ab0-4faa-ba22-1240eb24f34a' User entered '0'	System	11 Aug 2020 02:44:13
	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a699f82e-0ab0-4faa-ba22-1240eb24f34a' User entered '10 Aug 2020 22:44'	System	11 Aug 2020 02:44:13
	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	11 Aug 2020 02:44:13
User entered 'Day 8'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	11 Aug 2020 02:44:13
User entered 'Day 9'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:15', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '71dcaaf7-df10-475b-bee5-b3aa79089450' User entered 'None (1)'	System	04 Aug 2020 17:23:33
	System	04 Aug 2020 17:23:33

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:18', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '71dcaaf7-df10-475b-bee5-b3aa79089450' User entered 'No (N)'	System	04 Aug 2020 17:23:33
	System	04 Aug 2020 17:23:33

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:20', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '71dcaaf7-df10-475b-bee5-b3aa79089450' User entered 'No (N)'	System	04 Aug 2020 17:23:33
	System	04 Aug 2020 17:23:33

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '71dcaaf7-df10-475b-bee5-b3aa79089450' User entered 'None (1)'	System	04 Aug 2020 17:23:33
	System	04 Aug 2020 17:23:33

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:28', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '71dcaaf7-df10-475b-bee5-b3aa79089450' User entered '04 Aug 2020 13:23'	System	04 Aug 2020 17:23:33
	System	04 Aug 2020 17:23:33

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 13:15'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 15:45'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '10ea1167-e32a-49e8-b218-abf6a3cef62e' User entered 'None (1)'	System	05 Aug 2020 00:09:25
	System	05 Aug 2020 00:09:25

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '10ea1167-e32a-49e8-b218-abf6a3cef62e' User entered 'No (N)'	System	05 Aug 2020 00:09:25
	System	05 Aug 2020 00:09:25

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '10ea1167-e32a-49e8-b218-abf6a3cef62e' User entered 'No (N)'	System	05 Aug 2020 00:09:25
	System	05 Aug 2020 00:09:25

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:15', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '10ea1167-e32a-49e8-b218-abf6a3cef62e'	System	05 Aug 2020 00:09:25
User entered 'None (1)'	System	05 Aug 2020 00:09:25

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:22', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '10ea1167-e32a-49e8-b218-abf6a3cef62e' User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:09:25
	System	05 Aug 2020 00:09:25

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 16:40'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 2'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '60b1480d-327a-4553-8b94-f4184a77fdee'	System	06 Aug 2020 00:10:34
User entered 'None (1)'	System	06 Aug 2020 00:10:34

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '60b1480d-327a-4553-8b94-f4184a77fdee' User entered 'No (N)'	System	06 Aug 2020 00:10:34
	System	06 Aug 2020 00:10:34

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '60b1480d-327a-4553-8b94-f4184a77fdee' User entered 'No (N)'	System	06 Aug 2020 00:10:34
	System	06 Aug 2020 00:10:34

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:29', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '60b1480d-327a-4553-8b94-f4184a77fdee' User entered 'None (1)'	System	06 Aug 2020 00:10:34
	System	06 Aug 2020 00:10:34

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:32', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '60b1480d-327a-4553-8b94-f4184a77fdee' User entered '05 Aug 2020 20:10'	System	06 Aug 2020 00:10:34
	System	06 Aug 2020 00:10:34

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 3'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:18', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8a379a95-abb1-47b7-ae5d-cf0501e69a25'	System	07 Aug 2020 00:16:01
User entered 'None (1)'	System	07 Aug 2020 00:16:01

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:21', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8a379a95-abb1-47b7-ae5d-cf0501e69a25'	System	07 Aug 2020 00:16:01
User entered 'No (N)'	System	07 Aug 2020 00:16:01

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:50', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8a379a95-abb1-47b7-ae5d-cf0501e69a25' User entered 'No (N)'	System	07 Aug 2020 00:16:01
	System	07 Aug 2020 00:16:01

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:54', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8a379a95-abb1-47b7-ae5d-cf0501e69a25'	System	07 Aug 2020 00:16:01
User entered 'None (1)'	System	07 Aug 2020 00:16:01

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:15:59', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '8a379a95-abb1-47b7-ae5d-cf0501e69a25' User entered '06 Aug 2020 20:15'	System	07 Aug 2020 00:16:01
	System	07 Aug 2020 00:16:01

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 4'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c461bf1a-d330-4706-b1df-8cd8feb3ecc2' User entered 'None (1)'	System	08 Aug 2020 02:22:36
	System	08 Aug 2020 02:22:36

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:29', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c461bf1a-d330-4706-b1df-8cd8feb3ecc2' User entered 'No (N)'	System	08 Aug 2020 02:22:36
	System	08 Aug 2020 02:22:36

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:31', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c461bf1a-d330-4706-b1df-8cd8feb3ecc2'	System	08 Aug 2020 02:22:36
User entered 'No (N)'	System	08 Aug 2020 02:22:36

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:33', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c461bf1a-d330-4706-b1df-8cd8feb3ecc2' User entered 'None (1)'	System	08 Aug 2020 02:22:36
	System	08 Aug 2020 02:22:36

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:35', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c461bf1a-d330-4706-b1df-8cd8feb3ecc2' User entered '07 Aug 2020 22:22'	System	08 Aug 2020 02:22:36
	System	08 Aug 2020 02:22:36

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 5'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:34', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '59b582a8-2094-4b28-af4d-c4e52434698b' User entered 'None (1)'	System	09 Aug 2020 10:01:48
	System	09 Aug 2020 10:01:48

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '59b582a8-2094-4b28-af4d-c4e52434698b' User entered 'No (N)'	System	09 Aug 2020 10:01:48
	System	09 Aug 2020 10:01:48

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '59b582a8-2094-4b28-af4d-c4e52434698b' User entered 'No (N)'	System	09 Aug 2020 10:01:48
	System	09 Aug 2020 10:01:48

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:44', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '59b582a8-2094-4b28-af4d-c4e52434698b' User entered 'None (1)'	System	09 Aug 2020 10:01:48
	System	09 Aug 2020 10:01:48

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:46', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '59b582a8-2094-4b28-af4d-c4e52434698b' User entered '09 Aug 2020 06:01'	System	09 Aug 2020 10:01:48
	System	09 Aug 2020 10:01:48

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 6'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:05:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e0c97bc4-ca4e-426d-8e3a-1f0d3ed94b3d' User entered 'None (1)'	System	10 Aug 2020 00:06:18
	System	10 Aug 2020 00:06:18

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:05:49', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e0c97bc4-ca4e-426d-8e3a-1f0d3ed94b3d' User entered 'No (N)'	System	10 Aug 2020 00:06:18
	System	10 Aug 2020 00:06:18

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e0c97bc4-ca4e-426d-8e3a-1f0d3ed94b3d' User entered 'No (N)'	System	10 Aug 2020 00:06:18
	System	10 Aug 2020 00:06:18

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e0c97bc4-ca4e-426d-8e3a-1f0d3ed94b3d' User entered 'None (1)'	System	10 Aug 2020 00:06:18
	System	10 Aug 2020 00:06:18

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e0c97bc4-ca4e-426d-8e3a-1f0d3ed94b3d' User entered '09 Aug 2020 20:06'	System	10 Aug 2020 00:06:18
	System	10 Aug 2020 00:06:18

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 7'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:19', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b6872028-de86-4df3-8872-8bbfd93ebe0b' User entered 'None (1)'	System	11 Aug 2020 02:44:50
	System	11 Aug 2020 02:44:50

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:23', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b6872028-de86-4df3-8872-8bbfd93ebe0b' User entered 'No (N)'	System	11 Aug 2020 02:44:50
	System	11 Aug 2020 02:44:50

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b6872028-de86-4df3-8872-8bbfd93ebe0b' User entered 'No (N)'	System	11 Aug 2020 02:44:50
	System	11 Aug 2020 02:44:50

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:29', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b6872028-de86-4df3-8872-8bbfd93ebe0b' User entered 'None (1)'	System	11 Aug 2020 02:44:50
	System	11 Aug 2020 02:44:50

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:48', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'b6872028-de86-4df3-8872-8bbfd93ebe0b' User entered '10 Aug 2020 22:44'	System	11 Aug 2020 02:44:50
	System	11 Aug 2020 02:44:50

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:35', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered 'None (0)'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered 'None (0)'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:44', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered 'None (0)'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:47', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered 'None (0)'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:49', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered 'None (0)'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:51', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered 'None (0)'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered 'No (N)'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T13:23:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fa012184-6511-42a9-970e-cbcd52dea8ce' User entered '04 Aug 2020 13:23'	System	04 Aug 2020 17:24:01
	System	04 Aug 2020 17:24:01

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 13:15'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 15:45'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:38', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621'	System	05 Aug 2020 00:10:05
User entered 'No interference with activity (1)'	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:42', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621' User entered 'None (0)'	System	05 Aug 2020 00:10:05
	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621' User entered 'None (0)'	System	05 Aug 2020 00:10:05
	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:47', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621' User entered 'None (0)'	System	05 Aug 2020 00:10:05
	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:50', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621' User entered 'None (0)'	System	05 Aug 2020 00:10:05
	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:53', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621' User entered 'None (0)'	System	05 Aug 2020 00:10:05
	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:09:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621' User entered 'No (N)'	System	05 Aug 2020 00:10:05
	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-04T20:10:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'c8bf6ac5-52a1-4cec-a635-9631d8de7621' User entered '04 Aug 2020 20:10'	System	05 Aug 2020 00:10:05
	System	05 Aug 2020 00:10:05

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Aug 2020 16:40'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 2'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:38', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered 'None (0)'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:46', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered 'None (0)'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:48', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered 'None (0)'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:51', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered 'None (0)'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:53', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered 'None (0)'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered 'None (0)'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:10:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered 'No (N)'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-05T20:11:01', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '240202d7-f470-4d88-9393-6becf8d0f2ae' User entered '05 Aug 2020 20:11'	System	06 Aug 2020 00:11:03
	System	06 Aug 2020 00:11:03

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 3'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:16:19', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc'	System	07 Aug 2020 00:17:07
User entered 'No interference with activity (1)'	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:16:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc' User entered 'None (0)'	System	07 Aug 2020 00:17:07
	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:16:39', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc' User entered 'None (0)'	System	07 Aug 2020 00:17:07
	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:16:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc' User entered 'None (0)'	System	07 Aug 2020 00:17:07
	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:16:43', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc' User entered 'None (0)'	System	07 Aug 2020 00:17:07
	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:16:44', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc' User entered 'None (0)'	System	07 Aug 2020 00:17:07
	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:16:47', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc' User entered 'No (N)'	System	07 Aug 2020 00:17:07
	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-06T20:17:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'fd228fe6-840b-4be2-b47a-d9da02edb6cc' User entered '06 Aug 2020 20:17'	System	07 Aug 2020 00:17:07
	System	07 Aug 2020 00:17:07

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 4'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered 'None (0)'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:47', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered 'None (0)'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:49', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered 'None (0)'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:52', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered 'None (0)'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:54', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered 'None (0)'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered 'None (0)'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:22:57', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered 'No (N)'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-07T22:23:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3a97524b-379e-46ca-918c-2b179ef6ec15' User entered '07 Aug 2020 22:23'	System	08 Aug 2020 02:23:04
	System	08 Aug 2020 02:23:04

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 5'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:50', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b' User entered 'None (0)'	System	09 Aug 2020 10:02:13
	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b' User entered 'None (0)'	System	09 Aug 2020 10:02:13
	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:01:57', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b' User entered 'None (0)'	System	09 Aug 2020 10:02:13
	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:02:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b' User entered 'None (0)'	System	09 Aug 2020 10:02:13
	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:02:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b' User entered 'None (0)'	System	09 Aug 2020 10:02:13
	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:02:04', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b' User entered 'None (0)'	System	09 Aug 2020 10:02:13
	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:02:06', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b'	System	09 Aug 2020 10:02:13
User entered 'No (N)'	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T06:02:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'acc7ab36-7763-43d7-9ff8-ad1115fb598b' User entered '09 Aug 2020 06:02'	System	09 Aug 2020 10:02:13
	System	09 Aug 2020 10:02:13

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 6'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:21', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered 'None (0)'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:23', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered 'None (0)'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:25', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered 'None (0)'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:35', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered 'None (0)'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered 'None (0)'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:39', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered 'None (0)'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:43', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered 'No (N)'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-09T20:06:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adde98ba-5bd9-4ae1-bedc-3af19610a73e' User entered '09 Aug 2020 20:06'	System	10 Aug 2020 00:06:48
	System	10 Aug 2020 00:06:48

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 7'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359' User entered 'None (0)'	System	11 Aug 2020 02:45:39
	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:44:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359' User entered 'None (0)'	System	11 Aug 2020 02:45:39
	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:45:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359' User entered 'None (0)'	System	11 Aug 2020 02:45:39
	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:45:07', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359'	System	11 Aug 2020 02:45:39
User entered 'No interference with activity (1)'	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:45:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359' User entered 'None (0)'	System	11 Aug 2020 02:45:39
	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:45:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359' User entered 'None (0)'	System	11 Aug 2020 02:45:39
	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:45:30', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359' User entered 'No (N)'	System	11 Aug 2020 02:45:39
	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-08-10T22:45:34', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '470ccc5a-35e6-4698-a608-5dee59bea359' User entered '10 Aug 2020 22:45'	System	11 Aug 2020 02:45:39
	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	11 Aug 2020 02:45:39
User entered 'Day 8'	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:09:01

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	11 Aug 2020 02:45:39
User entered 'Day 9'	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:09:01

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 02:45:39

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	11 Aug 2020 02:44:13
User entered 'Day 8'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	11 Aug 2020 02:44:13
User entered 'Day 9'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 02:44:13

US3182151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 02:44:13

US3182151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:04:55
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:34:04

US3182151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:04:55
User entered '11 Aug 2020'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:34:04

US3182151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:04:55
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:34:04

US3182151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:04:55
User entered empty.	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:34:04

US3182151

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 23:34:15
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:34:11

US3182151

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'I'	System	20 Aug 2020 14:34:11

US3182151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:47
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:44:23

US3182151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:47
User entered '18 Aug 2020'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:44:23

US3182151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:47
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:44:23

US3182151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:47
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:44:23

US3182151

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 23:36:50
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:44:17

US3182151

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'I'	System	24 Aug 2020 13:44:17

US3182151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:11:40
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:19:09

US3182151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:11:40
User entered '25 Aug 2020'	Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:19:09

US3182151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:11:40
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:19:09

US3182151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:11:40
User entered empty.	Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:19:09

US3182151

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:11:54
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:19:01

US3182151

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'I'	System	26 Aug 2020 18:19:01

US3182151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:35
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:21

US3182151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:35
User entered '1 Sep 2020'	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:21

US3182151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:35
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:21

US3182151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'VISIT2'	System	01 Sep 2020 20:38:21

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	09 Sep 2020 20:21:58
	(b) (4)	

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '01 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '16:04'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '01 Sep 2020 16:04'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '98.3' F	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered empty.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '75'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'bpm'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '16'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'breaths/min'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '103'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '60'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '01 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '17:11'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '01 Sep 2020 17:11'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '98.3' F	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered empty.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '79'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'bpm'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '16'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'breaths/min'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '107'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:23:25
User entered '71'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	09 Sep 2020 20:21:58

US3182151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:25:00
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:11

US3182151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:25:00
User entered '01 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:11

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered '01 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered 'Urine (URINE)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered 'Negative (NEGATIVE)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
Query 'Query Text: Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).		19 Mar 2021 21:10:45
User opened query 'Query Text: Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).		19 Mar 2021 17:51:52
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered empty.	System	09 Sep 2020 20:22:53

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:14
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:14
User entered empty.	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:14
User entered empty.	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:14
User entered '1 Sep 2020'	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:14
User entered '16:36'	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '1 Sep 2020 16:36'	System	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:14
User entered 'Left Arm (LEFT ARM)'	Amy Maroun (b) (4) (b) (4)	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
DataPoint Verified.		29 Oct 2020 15:26:14
User entered 'ONCE'	System	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 20:38:41

US3182151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:01

US3182151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:44
User entered '01 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:01

US3182151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:44
User entered '16:15'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:01

US3182151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '01 Sep 2020 16:15'	System	09 Sep 2020 20:23:01

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:09:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:58
User entered '01 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:58
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:58
User entered '16:05'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '01 Sep 2020 16:05'	System	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:58
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:26:58
User entered empty.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered empty.	System	09 Sep 2020 20:22:26

US3182151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:27:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:23:05

US3182151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '1'	System	09 Sep 2020 20:23:05

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '816bd219-3dda-476c-ba8d-bb20d10a2e39'	System	01 Sep 2020 21:06:35
User entered 'Yes (Y)'	System	01 Sep 2020 21:06:35

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:23', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '816bd219-3dda-476c-ba8d-bb20d10a2e39' User entered '98.3'	System	01 Sep 2020 21:06:35
	System	01 Sep 2020 21:06:35

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:27', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '816bd219-3dda-476c-ba8d-bb20d10a2e39'	System	01 Sep 2020 21:06:35
User entered 'No (N)'	System	01 Sep 2020 21:06:35

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:30', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '816bd219-3dda-476c-ba8d-bb20d10a2e39'	System	01 Sep 2020 21:06:35
User entered '01 Sep 2020 17:06'	System	01 Sep 2020 21:06:35

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 16:56'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 19:26'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:28:53', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'eebc19df-b63b-4a23-915c-26ccc63b3c15' User entered 'Yes (Y)'	System	02 Sep 2020 04:29:14
	System	02 Sep 2020 04:29:14

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:28:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'eebc19df-b63b-4a23-915c-26ccc63b3c15' User entered '98.2'	System	02 Sep 2020 04:29:14
	System	02 Sep 2020 04:29:14

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:03', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'eebc19df-b63b-4a23-915c-26ccc63b3c15' User entered 'No (N)'	System	02 Sep 2020 04:29:14
	System	02 Sep 2020 04:29:14

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:08', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'eebc19df-b63b-4a23-915c-26ccc63b3c15' User entered '02 Sep 2020 00:29'	System	02 Sep 2020 04:29:14
	System	02 Sep 2020 04:29:14

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 20:21'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 2'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:11', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd96c01bf-447e-42b1-9bd5-8a073c7ed773' User entered 'Yes (Y)'	System	03 Sep 2020 04:04:42
	System	03 Sep 2020 04:04:42

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:24', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd96c01bf-447e-42b1-9bd5-8a073c7ed773' User entered '98.0'	System	03 Sep 2020 04:04:42
	System	03 Sep 2020 04:04:42

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd96c01bf-447e-42b1-9bd5-8a073c7ed773'	System	03 Sep 2020 04:04:42
User entered 'No (N)'	System	03 Sep 2020 04:04:42

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:39', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd96c01bf-447e-42b1-9bd5-8a073c7ed773'	System	03 Sep 2020 04:04:42
User entered '02 Sep 2020 21:04'	System	03 Sep 2020 04:04:42

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 3'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:06', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a5ea402e-3fd1-448c-9878-51e674ebe695' User entered 'Yes (Y)'	System	04 Sep 2020 04:38:18
	System	04 Sep 2020 04:38:18

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:11', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a5ea402e-3fd1-448c-9878-51e674ebe695' User entered '98.6'	System	04 Sep 2020 04:38:18
	System	04 Sep 2020 04:38:18

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:14', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a5ea402e-3fd1-448c-9878-51e674ebe695'	System	04 Sep 2020 04:38:18
User entered 'No (N)'	System	04 Sep 2020 04:38:18

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'a5ea402e-3fd1-448c-9878-51e674ebe695' User entered '03 Sep 2020 21:38'	System	04 Sep 2020 04:38:18
	System	04 Sep 2020 04:38:18

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 4'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:27', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'ae2d0215-a396-46c6-9627-66796edaebce' User entered 'Yes (Y)'	System	05 Sep 2020 02:05:48
	System	05 Sep 2020 02:05:48

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'ae2d0215-a396-46c6-9627-66796edaebce' User entered '98.7'	System	05 Sep 2020 02:05:48
	System	05 Sep 2020 02:05:48

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:40', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'ae2d0215-a396-46c6-9627-66796edaebce' User entered 'No (N)'	System	05 Sep 2020 02:05:48
	System	05 Sep 2020 02:05:48

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:44', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'ae2d0215-a396-46c6-9627-66796edaebce' User entered '04 Sep 2020 19:05'	System	05 Sep 2020 02:05:48
	System	05 Sep 2020 02:05:48

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 5'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3c3e155c-200b-4769-adff-e0029ba7c4be' User entered 'Yes (Y)'	System	06 Sep 2020 02:02:28
	System	06 Sep 2020 02:02:28

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3c3e155c-200b-4769-adff-e0029ba7c4be' User entered '98.4'	System	06 Sep 2020 02:02:28
	System	06 Sep 2020 02:02:28

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:21', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3c3e155c-200b-4769-adff-e0029ba7c4be' User entered 'No (N)'	System	06 Sep 2020 02:02:28
	System	06 Sep 2020 02:02:28

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3c3e155c-200b-4769-adff-e0029ba7c4be' User entered '05 Sep 2020 19:02'	System	06 Sep 2020 02:02:28
	System	06 Sep 2020 02:02:28

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 6'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:01:31', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e215ee94-19b1-4c8d-a89c-e378afa007c8' User entered 'Yes (Y)'	System	07 Sep 2020 02:01:45
	System	07 Sep 2020 02:01:45

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:01:38', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e215ee94-19b1-4c8d-a89c-e378afa007c8' User entered '98.6'	System	07 Sep 2020 02:01:45
	System	07 Sep 2020 02:01:45

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:01:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e215ee94-19b1-4c8d-a89c-e378afa007c8' User entered 'No (N)'	System	07 Sep 2020 02:01:45
	System	07 Sep 2020 02:01:45

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:01:43', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e215ee94-19b1-4c8d-a89c-e378afa007c8' User entered '06 Sep 2020 22:01'	System	07 Sep 2020 02:01:45
	System	07 Sep 2020 02:01:45

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 7'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:43:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '5859d964-cad1-4a49-8439-33d9c89b0fe6' User entered 'Yes (Y)'	System	08 Sep 2020 01:44:06
	System	08 Sep 2020 01:44:06

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:43:59', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '5859d964-cad1-4a49-8439-33d9c89b0fe6' User entered '98.5'	System	08 Sep 2020 01:44:06
	System	08 Sep 2020 01:44:06

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '5859d964-cad1-4a49-8439-33d9c89b0fe6' User entered 'No (N)'	System	08 Sep 2020 01:44:06
	System	08 Sep 2020 01:44:06

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:04', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '5859d964-cad1-4a49-8439-33d9c89b0fe6' User entered '07 Sep 2020 21:44'	System	08 Sep 2020 01:44:06
	System	08 Sep 2020 01:44:06

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:43', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '198b52fd-e25e-47cc-8fd0-c44dafcc36cb' User entered 'None (1)'	System	01 Sep 2020 21:06:56
	System	01 Sep 2020 21:06:56

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:47', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '198b52fd-e25e-47cc-8fd0-c44dafcc36cb' User entered 'No (N)'	System	01 Sep 2020 21:06:56
	System	01 Sep 2020 21:06:56

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:49', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '198b52fd-e25e-47cc-8fd0-c44dafcc36cb' User entered 'No (N)'	System	01 Sep 2020 21:06:56
	System	01 Sep 2020 21:06:56

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:52', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '198b52fd-e25e-47cc-8fd0-c44dafcc36cb'	System	01 Sep 2020 21:06:56
User entered 'None (1)'	System	01 Sep 2020 21:06:56

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:54', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '198b52fd-e25e-47cc-8fd0-c44dafcc36cb' User entered '01 Sep 2020 17:06'	System	01 Sep 2020 21:06:56
	System	01 Sep 2020 21:06:56

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 16:56'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 19:26'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '02680a14-a521-451c-8e7d-563fbb01b84e' User entered 'None (1)'	System	02 Sep 2020 04:29:25
	System	02 Sep 2020 04:29:25

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:15', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '02680a14-a521-451c-8e7d-563fbb01b84e' User entered 'No (N)'	System	02 Sep 2020 04:29:25
	System	02 Sep 2020 04:29:25

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '02680a14-a521-451c-8e7d-563fbb01b84e' User entered 'No (N)'	System	02 Sep 2020 04:29:25
	System	02 Sep 2020 04:29:25

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:19', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '02680a14-a521-451c-8e7d-563fbb01b84e' User entered 'None (1)'	System	02 Sep 2020 04:29:25
	System	02 Sep 2020 04:29:25

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:21', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '02680a14-a521-451c-8e7d-563fbb01b84e' User entered '02 Sep 2020 00:29'	System	02 Sep 2020 04:29:25
	System	02 Sep 2020 04:29:25

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 20:21'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 2'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '218e2fb7-0dbc-4ccd-b30a-38e71f307ec8'	System	03 Sep 2020 04:05:08
User entered 'None (1)'	System	03 Sep 2020 04:05:08

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:48', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '218e2fb7-0dbc-4ccd-b30a-38e71f307ec8' User entered 'No (N)'	System	03 Sep 2020 04:05:08
	System	03 Sep 2020 04:05:08

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:50', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '218e2fb7-0dbc-4ccd-b30a-38e71f307ec8' User entered 'No (N)'	System	03 Sep 2020 04:05:08
	System	03 Sep 2020 04:05:08

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:04:52', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '218e2fb7-0dbc-4ccd-b30a-38e71f307ec8' User entered 'None (1)'	System	03 Sep 2020 04:05:08
	System	03 Sep 2020 04:05:08

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:04', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '218e2fb7-0dbc-4ccd-b30a-38e71f307ec8' User entered '02 Sep 2020 21:05'	System	03 Sep 2020 04:05:08
	System	03 Sep 2020 04:05:08

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 3'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:21', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4dedc2e5-6026-4684-b859-43715ab1d8a3'	System	04 Sep 2020 04:38:34
User entered 'None (1)'	System	04 Sep 2020 04:38:34

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:24', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4dedc2e5-6026-4684-b859-43715ab1d8a3' User entered 'No (N)'	System	04 Sep 2020 04:38:34
	System	04 Sep 2020 04:38:34

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:25', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4dedc2e5-6026-4684-b859-43715ab1d8a3' User entered 'No (N)'	System	04 Sep 2020 04:38:34
	System	04 Sep 2020 04:38:34

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:27', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4dedc2e5-6026-4684-b859-43715ab1d8a3'	System	04 Sep 2020 04:38:34
User entered 'None (1)'	System	04 Sep 2020 04:38:34

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:31', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4dedc2e5-6026-4684-b859-43715ab1d8a3' User entered '03 Sep 2020 21:38'	System	04 Sep 2020 04:38:34
	System	04 Sep 2020 04:38:34

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 4'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:48', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '1c62dc7d-3e03-45b2-a509-2606cb5cbe94'	System	05 Sep 2020 02:06:01
User entered 'None (1)'	System	05 Sep 2020 02:06:01

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:51', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '1c62dc7d-3e03-45b2-a509-2606cb5cbe94' User entered 'No (N)'	System	05 Sep 2020 02:06:01
	System	05 Sep 2020 02:06:01

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:52', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '1c62dc7d-3e03-45b2-a509-2606cb5cbe94' User entered 'No (N)'	System	05 Sep 2020 02:06:01
	System	05 Sep 2020 02:06:01

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '1c62dc7d-3e03-45b2-a509-2606cb5cbe94'	System	05 Sep 2020 02:06:01
User entered 'None (1)'	System	05 Sep 2020 02:06:01

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:05:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '1c62dc7d-3e03-45b2-a509-2606cb5cbe94' User entered '04 Sep 2020 19:05'	System	05 Sep 2020 02:06:01
	System	05 Sep 2020 02:06:01

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 5'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:31', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '7651655f-5e18-4d3c-b779-e16f62e7bb8a' User entered 'None (1)'	System	06 Sep 2020 02:02:43
	System	06 Sep 2020 02:02:43

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:33', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '7651655f-5e18-4d3c-b779-e16f62e7bb8a' User entered 'No (N)'	System	06 Sep 2020 02:02:43
	System	06 Sep 2020 02:02:43

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:35', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '7651655f-5e18-4d3c-b779-e16f62e7bb8a' User entered 'No (N)'	System	06 Sep 2020 02:02:43
	System	06 Sep 2020 02:02:43

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '7651655f-5e18-4d3c-b779-e16f62e7bb8a' User entered 'None (1)'	System	06 Sep 2020 02:02:43
	System	06 Sep 2020 02:02:43

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '7651655f-5e18-4d3c-b779-e16f62e7bb8a' User entered '05 Sep 2020 19:02'	System	06 Sep 2020 02:02:43
	System	06 Sep 2020 02:02:43

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 6'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:01:48', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0337e59d-c345-4402-a1d0-855ccb162e5b' User entered 'None (1)'	System	07 Sep 2020 02:02:14
	System	07 Sep 2020 02:02:14

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:01:52', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0337e59d-c345-4402-a1d0-855ccb162e5b' User entered 'No (N)'	System	07 Sep 2020 02:02:14
	System	07 Sep 2020 02:02:14

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:01:54', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0337e59d-c345-4402-a1d0-855ccb162e5b' User entered 'No (N)'	System	07 Sep 2020 02:02:14
	System	07 Sep 2020 02:02:14

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:06', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0337e59d-c345-4402-a1d0-855ccb162e5b' User entered 'None (1)'	System	07 Sep 2020 02:02:14
	System	07 Sep 2020 02:02:14

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '0337e59d-c345-4402-a1d0-855ccb162e5b' User entered '06 Sep 2020 22:02'	System	07 Sep 2020 02:02:14
	System	07 Sep 2020 02:02:14

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 7'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:08', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3ef6402f-4290-4a59-a4a2-cf9c2da8ec25'	System	08 Sep 2020 01:44:40
User entered 'None (1)'	System	08 Sep 2020 01:44:40

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:11', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3ef6402f-4290-4a59-a4a2-cf9c2da8ec25'	System	08 Sep 2020 01:44:40
User entered 'No (N)'	System	08 Sep 2020 01:44:40

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:13', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3ef6402f-4290-4a59-a4a2-cf9c2da8ec25'	System	08 Sep 2020 01:44:40
User entered 'No (N)'	System	08 Sep 2020 01:44:40

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:16', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3ef6402f-4290-4a59-a4a2-cf9c2da8ec25'	System	08 Sep 2020 01:44:40
User entered 'None (1)'	System	08 Sep 2020 01:44:40

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:36', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3ef6402f-4290-4a59-a4a2-cf9c2da8ec25'	System	08 Sep 2020 01:44:40
User entered '07 Sep 2020 21:44'	System	08 Sep 2020 01:44:40

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:06:59', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered 'None (0)'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:07:01', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered 'None (0)'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:07:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered 'None (0)'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:07:04', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered 'None (0)'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:07:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered 'None (0)'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:07:07', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered 'None (0)'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:07:11', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered 'No (N)'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-01T17:07:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '2fe3b149-aa39-4fed-a041-6b46061ffa3f' User entered '01 Sep 2020 17:07'	System	01 Sep 2020 21:07:16
	System	01 Sep 2020 21:07:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 16:56'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 19:26'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:25', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered 'None (0)'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:27', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered 'None (0)'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:29', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered 'None (0)'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:31', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered 'None (0)'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:33', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered 'None (0)'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:35', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered 'None (0)'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:46', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered 'No (N)'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T00:29:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'cdde759d-9083-4923-9d58-56f232cbded8' User entered '02 Sep 2020 00:29'	System	02 Sep 2020 04:30:02
	System	02 Sep 2020 04:30:02

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '01 Sep 2020 20:21'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 2'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:34', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd' User entered 'None (0)'	System	03 Sep 2020 04:05:58
	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:36', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd' User entered 'None (0)'	System	03 Sep 2020 04:05:58
	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:38', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd' User entered 'None (0)'	System	03 Sep 2020 04:05:58
	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd' User entered 'None (0)'	System	03 Sep 2020 04:05:58
	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:43', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd' User entered 'None (0)'	System	03 Sep 2020 04:05:58
	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:46', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd' User entered 'None (0)'	System	03 Sep 2020 04:05:58
	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:53', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd'	System	03 Sep 2020 04:05:58
User entered 'No (N)'	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-02T21:05:56', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be954744-6244-4902-af9f-e6f13b2fb9dd' User entered '02 Sep 2020 21:05'	System	03 Sep 2020 04:05:58
	System	03 Sep 2020 04:05:58

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 3'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:38', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered 'None (0)'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:40', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered 'None (0)'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:42', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered 'None (0)'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:56', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered 'None (0)'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:38:59', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered 'None (0)'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:39:01', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered 'None (0)'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:39:04', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered 'No (N)'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-03T21:39:06', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '023afebe-63d9-4706-9c48-ffbc00a183b2' User entered '03 Sep 2020 21:39'	System	04 Sep 2020 04:39:09
	System	04 Sep 2020 04:39:09

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 4'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487' User entered 'None (0)'	System	05 Sep 2020 02:06:26
	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:08', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487' User entered 'None (0)'	System	05 Sep 2020 02:06:26
	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:10', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487' User entered 'None (0)'	System	05 Sep 2020 02:06:26
	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:11', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487' User entered 'None (0)'	System	05 Sep 2020 02:06:26
	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:13', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487' User entered 'None (0)'	System	05 Sep 2020 02:06:26
	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:16', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487' User entered 'None (0)'	System	05 Sep 2020 02:06:26
	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:19', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487'	System	05 Sep 2020 02:06:26
User entered 'No (N)'	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-04T19:06:25', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '4e74f4f9-75ff-4fa2-b57b-e80295ab7487'	System	05 Sep 2020 02:06:26
User entered '04 Sep 2020 19:06'	System	05 Sep 2020 02:06:26

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 5'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:44', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered 'None (0)'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:52', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered 'None (0)'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:56', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered 'None (0)'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:02:59', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered 'None (0)'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:03:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered 'None (0)'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:03:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered 'None (0)'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:03:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered 'No (N)'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-05T19:03:08', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '84f280c5-a4bf-4abb-b8a5-f988f8447c14' User entered '05 Sep 2020 19:03'	System	06 Sep 2020 02:03:16
	System	06 Sep 2020 02:03:16

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 6'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:13', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51' User entered 'None (0)'	System	07 Sep 2020 02:02:35
	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:15', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51' User entered 'None (0)'	System	07 Sep 2020 02:02:35
	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51' User entered 'None (0)'	System	07 Sep 2020 02:02:35
	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:18', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51' User entered 'None (0)'	System	07 Sep 2020 02:02:35
	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:20', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51' User entered 'None (0)'	System	07 Sep 2020 02:02:35
	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:22', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51' User entered 'None (0)'	System	07 Sep 2020 02:02:35
	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51'	System	07 Sep 2020 02:02:35
User entered 'No (N)'	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-06T22:02:29', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'afdfa4b3-0827-4c1e-a6e1-a78c0a990f51' User entered '06 Sep 2020 22:02'	System	07 Sep 2020 02:02:35
	System	07 Sep 2020 02:02:35

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	01 Sep 2020 20:38:41
User entered 'Day 7'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:39', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered 'None (0)'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:42', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered 'None (0)'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:43', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered 'None (0)'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered 'None (0)'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:47', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered 'None (0)'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:48', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered 'None (0)'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

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 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:53', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered 'No (N)'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-09-07T21:44:55', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '6d69ffec-5ac1-4604-8aa1-b86c843251ea' User entered '07 Sep 2020 21:44'	System	08 Sep 2020 01:44:59
	System	08 Sep 2020 01:44:59

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:38:41

US3182151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:38:41

US3182151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:12
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:11:53

US3182151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:12
User entered '8 Sep 2020'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:11:53

US3182151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:12
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:11:53

US3182151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:12
User entered empty.	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:11:53

US3182151

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:18
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:11:59

US3182151

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'I'	System	10 Sep 2020 18:11:59

US3182151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:35
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:43:26

US3182151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:35
User entered '15 Sep 2020'	Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:43:26

US3182151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:35
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:43:26

US3182151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:35
User entered empty.	Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:43:26

US3182151

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:44
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	16 Sep 2020 17:43:30

US3182151

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'I'	System	16 Sep 2020 17:43:30

US3182151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
User closed query 'Please complete source. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:19:48
Query 'Please complete source. ' answered with 'updated' (Site from CRA). DataPoint Verified.	Amy Maroun (b) (4) (b) (4) (b) (4), (b) (6)	29 Oct 2020 12:18:29 15 Oct 2020 15:54:41
User opened query 'Please complete source. ' (Site from CRA).		15 Oct 2020 15:54:31
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:48:48

US3182151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:54:41
User entered '22 Sep 2020'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:48:48

US3182151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:54:41
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:48:48

US3182151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:54:41
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:48:48

US3182151

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:55:32
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:48:52

US3182151

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'I'	System	24 Sep 2020 16:48:52

US3182151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:28:59
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:26

US3182151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:28:59
User entered '29 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:26

US3182151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:28:59
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:26

US3182151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'VISIT3'	System	29 Sep 2020 19:10:26

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered '29 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered '14:14'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '29 Sep 2020 14:14'	System	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered '99.3' F	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered '80'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'bpm'	System	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered '16'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'breaths/min'	System	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered '121'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:30
User entered '77'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'mmHg'	System	29 Sep 2020 19:10:55

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41

US3182151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41

US3182151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:43
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:11:14

US3182151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:43
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:11:14

US3182151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:11:27

US3182151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:21
User entered '29 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:11:27

US3182151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:21
User entered '14:23'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:11:27

US3182151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '29 Sep 2020 14:23'	System	29 Sep 2020 19:11:27

US3182151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:30:29
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:11:31

US3182151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered '1'	System	29 Sep 2020 19:11:31

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 64'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-05T12:55:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '63c3d34c-4be3-4590-8ad8-97498d42e35f'	System	05 Oct 2020 16:55:18
User entered 'No (N)'	System	05 Oct 2020 16:55:18

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-05T12:55:10', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '63c3d34c-4be3-4590-8ad8-97498d42e35f'	System	05 Oct 2020 16:55:18
User entered 'No (N)'	System	05 Oct 2020 16:55:18

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-05T12:55:15', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '63c3d34c-4be3-4590-8ad8-97498d42e35f' User entered '05 Oct 2020 12:55:15'	System	05 Oct 2020 16:55:18
	System	05 Oct 2020 16:55:18

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 71'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-11T08:53:13', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '926aa259-b68a-4f7d-9a03-7a1f29a45e3e'	System	11 Oct 2020 12:53:25
User entered 'No (N)'	System	11 Oct 2020 12:53:25

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-11T08:53:16', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '926aa259-b68a-4f7d-9a03-7a1f29a45e3e'	System	11 Oct 2020 12:53:25
User entered 'No (N)'	System	11 Oct 2020 12:53:25

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-11T08:53:20', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '926aa259-b68a-4f7d-9a03-7a1f29a45e3e' User entered '11 Oct 2020 08:53:20'	System	11 Oct 2020 12:53:25
	System	11 Oct 2020 12:53:25

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 78'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-19T14:11:53', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '53ac3f7b-c3a9-4e60-8426-490232bbfcdc' User entered 'No (N)'	System	19 Oct 2020 18:22:10
	System	19 Oct 2020 18:22:10

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-19T14:11:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '53ac3f7b-c3a9-4e60-8426-490232bbfcdc'	System	19 Oct 2020 18:22:10
User entered 'No (N)'	System	19 Oct 2020 18:22:10

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-10-19T14:12:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '53ac3f7b-c3a9-4e60-8426-490232bbfcdc' User entered '19 Oct 2020 14:12:02'	System	19 Oct 2020 18:22:10
	System	19 Oct 2020 18:22:10

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 92'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-01T09:05:32', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '44c64980-be55-46e8-bbac-0290205f4551'	System	01 Nov 2020 14:05:40
User entered 'No (N)'	System	01 Nov 2020 14:05:40

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-01T09:05:35', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '44c64980-be55-46e8-bbac-0290205f4551'	System	01 Nov 2020 14:05:40
User entered 'No (N)'	System	01 Nov 2020 14:05:40

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-01T09:05:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '44c64980-be55-46e8-bbac-0290205f4551' User entered '01 Nov 2020 09:05:37'	System	01 Nov 2020 14:05:40
	System	01 Nov 2020 14:05:40

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 99'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-11T21:50:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adc45bd3-ce3c-41b8-bab9-0d5ffe74b4d2'	System	12 Nov 2020 02:50:15
User entered 'No (N)'	System	12 Nov 2020 02:50:15

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-11T21:50:08', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adc45bd3-ce3c-41b8-bab9-0d5ffe74b4d2'	System	12 Nov 2020 02:50:15
User entered 'No (N)'	System	12 Nov 2020 02:50:15

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-11T21:50:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'adc45bd3-ce3c-41b8-bab9-0d5ffe74b4d2' User entered '11 Nov 2020 21:50:12'	System	12 Nov 2020 02:50:15
	System	12 Nov 2020 02:50:15

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered 'Day 106'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-17T12:09:22', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '79808e47-5bcc-4826-95ce-7f4c04b09a56'	System	17 Nov 2020 17:09:29
User entered 'No (N)'	System	17 Nov 2020 17:09:29

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-17T12:09:25', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '79808e47-5bcc-4826-95ce-7f4c04b09a56'	System	17 Nov 2020 17:09:29
User entered 'No (N)'	System	17 Nov 2020 17:09:29

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-17T12:09:27', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '79808e47-5bcc-4826-95ce-7f4c04b09a56' User entered '17 Nov 2020 12:09:27'	System	17 Nov 2020 17:09:29
	System	17 Nov 2020 17:09:29

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 16:57:52

US3182151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:11
Data entry locked.	System	04 Aug 2020 16:57:52
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 16:57:52

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-23T20:21:54', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '00d4ae2c-75a7-4183-af5a-147d51241a84'	System	24 Nov 2020 01:22:09
User entered 'No (N)'	System	24 Nov 2020 01:22:09

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-23T20:22:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '00d4ae2c-75a7-4183-af5a-147d51241a84'	System	24 Nov 2020 01:22:09
User entered 'No (N)'	System	24 Nov 2020 01:22:09

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-23T20:22:07', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '00d4ae2c-75a7-4183-af5a-147d51241a84' User entered '23 Nov 2020 20:22:07'	System	24 Nov 2020 01:22:09
	System	24 Nov 2020 01:22:09

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-27T18:14:56', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '30b552e7-5d38-4d96-8fe4-d5cb7c7f0b5d' User entered 'No (N)'	System	27 Nov 2020 23:15:04
	System	27 Nov 2020 23:15:04

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-27T18:14:58', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '30b552e7-5d38-4d96-8fe4-d5cb7c7f0b5d' User entered 'No (N)'	System	27 Nov 2020 23:15:04
	System	27 Nov 2020 23:15:04

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-11-27T18:15:01', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '30b552e7-5d38-4d96-8fe4-d5cb7c7f0b5d' User entered '27 Nov 2020 18:15:01'	System	27 Nov 2020 23:15:04
	System	27 Nov 2020 23:15:04

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-07T10:43:09', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd765168a-11d5-41e2-8ae4-3af3433fd98c' User entered 'No (N)'	System	07 Dec 2020 15:43:51
	System	07 Dec 2020 15:43:51

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-07T10:43:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd765168a-11d5-41e2-8ae4-3af3433fd98c' User entered 'No (N)'	System	07 Dec 2020 15:43:51
	System	07 Dec 2020 15:43:51

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-07T10:43:49', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd765168a-11d5-41e2-8ae4-3af3433fd98c' User entered '07 Dec 2020 10:43:49'	System	07 Dec 2020 15:43:51
	System	07 Dec 2020 15:43:51

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Please 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 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Please 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 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Please 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 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-17T03:58:28', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e948673f-6530-4060-9d5e-bdc11a4dca4c' User entered 'No (N)'	System	17 Dec 2020 08:58:48
	System	17 Dec 2020 08:58:48

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-17T03:58:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e948673f-6530-4060-9d5e-bdc11a4dca4c'	System	17 Dec 2020 08:58:48
User entered 'No (N)'	System	17 Dec 2020 08:58:48

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-17T03:58:45', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'e948673f-6530-4060-9d5e-bdc11a4dca4c' User entered '17 Dec 2020 03:58:45'	System	17 Dec 2020 08:58:48
	System	17 Dec 2020 08:58:48

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-24T12:49:08', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'ec0c093b-4433-408a-b78e-89778f59ace0' User entered 'No (N)'	System	24 Dec 2020 17:49:23
	System	24 Dec 2020 17:49:23

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-24T12:49:16', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'ec0c093b-4433-408a-b78e-89778f59ace0'	System	24 Dec 2020 17:49:23
User entered 'No (N)'	System	24 Dec 2020 17:49:23

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-24T12:49:20', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'ec0c093b-4433-408a-b78e-89778f59ace0' User entered '24 Dec 2020 12:49:20'	System	24 Dec 2020 17:49:23
	System	24 Dec 2020 17:49:23

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-31T10:33:12', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '558563e8-c2a9-490b-8144-2567287deb71'	System	31 Dec 2020 15:33:45
User entered 'No (N)'	System	31 Dec 2020 15:33:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-31T10:33:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '558563e8-c2a9-490b-8144-2567287deb71'	System	31 Dec 2020 15:33:45
User entered 'No (N)'	System	31 Dec 2020 15:33:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2020-12-31T10:33:40', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '558563e8-c2a9-490b-8144-2567287deb71' User entered '31 Dec 2020 10:33:40'	System	31 Dec 2020 15:33:45
	System	31 Dec 2020 15:33:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-08T15:51:13', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '524c7891-e5c4-4960-b94b-9b71b0aa2581' User entered 'No (N)'	System	08 Jan 2021 20:51:45
	System	08 Jan 2021 20:51:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-08T15:51:17', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '524c7891-e5c4-4960-b94b-9b71b0aa2581'	System	08 Jan 2021 20:51:45
User entered 'Yes (Y)'	System	08 Jan 2021 20:51:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Please 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-08T15:51:31', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '524c7891-e5c4-4960-b94b-9b71b0aa2581'	System	08 Jan 2021 20:51:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 20:51:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-08T15:51:36', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '524c7891-e5c4-4960-b94b-9b71b0aa2581' User entered '08 Jan 2021 15:51:36'	System	08 Jan 2021 20:51:45
	System	08 Jan 2021 20:51:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-14T11:55:51', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '493ca42c-8bf3-4ed9-a529-1f12c99552ae'	System	14 Jan 2021 16:56:04
User entered 'No (N)'	System	14 Jan 2021 16:56:04

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-14T11:55:56', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '493ca42c-8bf3-4ed9-a529-1f12c99552ae'	System	14 Jan 2021 16:56:04
User entered 'No (N)'	System	14 Jan 2021 16:56:04

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-14T11:55:59', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '493ca42c-8bf3-4ed9-a529-1f12c99552ae' User entered '14 Jan 2021 11:55:59'	System	14 Jan 2021 16:56:04
	System	14 Jan 2021 16:56:04

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-23T12:02:05', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'dc00cf11-70df-455d-a138-258cb321b985'	System	23 Jan 2021 20:02:34
User entered 'No (N)'	System	23 Jan 2021 20:02:34

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-23T12:02:27', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'dc00cf11-70df-455d-a138-258cb321b985'	System	23 Jan 2021 20:02:34
User entered 'No (N)'	System	23 Jan 2021 20:02:34

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-23T12:02:30', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'dc00cf11-70df-455d-a138-258cb321b985' User entered '23 Jan 2021 12:02:30'	System	23 Jan 2021 20:02:34
	System	23 Jan 2021 20:02:34

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-31T21:06:23', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3d98731e-336d-45de-b865-4bdfffd3242a' User entered 'No (N)'	System	01 Feb 2021 02:09:10
	System	01 Feb 2021 02:09:10

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-31T21:06:29', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3d98731e-336d-45de-b865-4bdfffd3242a' User entered 'No (N)'	System	01 Feb 2021 02:09:10

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-01-31T21:06:41', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '3d98731e-336d-45de-b865-4bdfffd3242a' User entered '31 Jan 2021 21:06:41'	System	01 Feb 2021 02:09:10
	System	01 Feb 2021 02:09:10

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-04T07:23:34', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '922d580d-5090-4ed1-a1da-0b7939a39920'	System	04 Feb 2021 12:23:45
User entered 'No (N)'	System	04 Feb 2021 12:23:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-04T07:23:37', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '922d580d-5090-4ed1-a1da-0b7939a39920'	System	04 Feb 2021 12:23:45
User entered 'No (N)'	System	04 Feb 2021 12:23:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-04T07:23:40', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '922d580d-5090-4ed1-a1da-0b7939a39920' User entered '04 Feb 2021 07:23:40'	System	04 Feb 2021 12:23:45
	System	04 Feb 2021 12:23:45

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-11T10:55:18', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '544fa209-1af3-491d-8b2e-679d8e306acf' User entered 'No (N)'	System	11 Feb 2021 15:55:29
	System	11 Feb 2021 15:55:29

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-11T10:55:23', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '544fa209-1af3-491d-8b2e-679d8e306acf'	System	11 Feb 2021 15:55:29
User entered 'No (N)'	System	11 Feb 2021 15:55:29

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-11T10:55:26', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '544fa209-1af3-491d-8b2e-679d8e306acf' User entered '11 Feb 2021 10:55:26'	System	11 Feb 2021 15:55:29
	System	11 Feb 2021 15:55:29

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-18T06:22:02', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be698d42-1281-42aa-bb6f-4585e596d4d7'	System	18 Feb 2021 11:22:15
User entered 'No (N)'	System	18 Feb 2021 11:22:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-18T06:22:06', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be698d42-1281-42aa-bb6f-4585e596d4d7'	System	18 Feb 2021 11:22:15
User entered 'No (N)'	System	18 Feb 2021 11:22:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-02-18T06:22:10', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'be698d42-1281-42aa-bb6f-4585e596d4d7' User entered '18 Feb 2021 06:22:10'	System	18 Feb 2021 11:22:15
	System	18 Feb 2021 11:22:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-03-01T12:05:34-05:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '5eec845c-193a-4bf2-9722-7c9375a640ab' User entered 'No (N)'	System	01 Mar 2021 17:18:54
	System	01 Mar 2021 17:18:54

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-03-01T12:05:36-05:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '5eec845c-193a-4bf2-9722-7c9375a640ab' User entered 'No (N)'	System	01 Mar 2021 17:18:54
	System	01 Mar 2021 17:18:54

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-03-01T12:05:38-05:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: '5eec845c-193a-4bf2-9722-7c9375a640ab' User entered '01 Mar 2021 12:05:38'	System	01 Mar 2021 17:18:54
	System	01 Mar 2021 17:18:54

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Have you been exposed to someone with 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Have you been exposed to someone with 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

Please 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 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:33:15

US3182151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
DataPoint Activated.	System	22 Apr 2021 20:44:18
DataPoint Inactivated.	System	25 Mar 2021 17:08:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:33:15
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:33:15

US3182151

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:09:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-03-01T12:05:42-05:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd0a7961e-a819-494a-aec5-ed49891c8100'	System	01 Mar 2021 17:19:08
User entered 'No (N)'	System	01 Mar 2021 17:19:08

US3182151

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:09:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31409A95-E631-47E5-9F85-E5863044A756)', Time: '2021-03-01T12:05:47-05:00', User OID: 'PatientReportedOutcome (US3182151)', ODM File OID: 'd0a7961e-a819-494a-aec5-ed49891c8100'	System	01 Mar 2021 17:19:08
User entered '01 Mar 2021 12:05:47'	System	01 Mar 2021 17:19:08

US3182151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:57:00
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 14:40:23

US3182151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:57:00
User entered '27 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 14:40:23

US3182151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:57:00
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 14:40:23

US3182151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:57:00
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 14:40:23

US3182151

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:57:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Oct 2020 14:40:34

US3182151

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:59:41
User entered 'I'	System	29 Oct 2020 14:40:34

US3182151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:32:36
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Dec 2020 02:52:27

US3182151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:32:36
User entered '01 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	10 Dec 2020 02:52:27

US3182151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:32:36
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	10 Dec 2020 02:52:27

US3182151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:32:36
User entered empty.	Cassie Uminski (b) (4) (b) (4)	10 Dec 2020 02:52:27

US3182151

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:32:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Dec 2020 02:52:06

US3182151

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User entered '1'	System	10 Dec 2020 02:52:06

US3182151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:52:24
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:36:37

US3182151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:52:24
User entered '28 Dec 2020'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:36:37

US3182151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:52:24
User entered 'Contact Made (CONTACT MADE)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:36:37

US3182151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:52:24
User entered empty.	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:36:37

US3182151

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:52:29
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:36:46

US3182151

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User entered 'I'	System	05 Jan 2021 15:36:46

US3182151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:16:57
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	28 Jan 2021 14:14:09

US3182151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:16:57
User entered '26 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	28 Jan 2021 14:14:09

US3182151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:16:57
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	28 Jan 2021 14:14:09

US3182151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:25:18
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 00:16:57
User entered empty.	Cassie Uminski (b) (4) (b) (4)	28 Jan 2021 14:14:09

US3182151

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:29
User signature succeeded.	Toby Briskin (b) (4)	28 Apr 2021 22:33:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:44:52
User closed query 'As subject did not attend V4, this should be no so V4 doesn't populate. Please update as appropriate. ' (Site from CRA).		28 Apr 2021 20:44:49
Query 'As subject did not attend V4, this should be no so V4 doesn't populate. Please update as appropriate. ' answered with 'updated' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	28 Apr 2021 20:44:03
Signature has been broken.	Naqib Ahmad (b) (4) (b) (4)	28 Apr 2021 20:43:56
User entered 'No (N)' reason for change: Data Entry Error	Naqib Ahmad (b) (4) (b) (4)	28 Apr 2021 20:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 12:09:23
User opened query 'As subject did not attend V4, this should be no so V4 doesn't populate. Please update as appropriate. ' (Site from CRA).		26 Apr 2021 19:13:45
User closed query 'Should this be no? Why wasn't V4 completed?' (Site from CRA).		26 Apr 2021 19:13:45
Query 'Should this be no? Why wasn't V4 completed?' answered with 'At this point in the study- the subject was still continuing, it wasn't until OL-1 that it was confirmed the subject would not continue. V4 was not completed as at the time of the OL-1 visit, it was not within the window for that visit ' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 16:46:48
User opened query 'Should this be no? Why wasn't V4 completed?' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:56:04
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 00:17:04

US3182151

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	28 Jan 2021 14:14:15

US3182151

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:29
User entered empty.	System	28 Apr 2021 20:43:56
User entered 'I'	System	28 Jan 2021 14:14:15

US3182151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:34
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:55:28

US3182151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:34
User entered '04 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:55:28

US3182151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:34
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:55:28

US3182151

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

Form: Visit Date

Generated On: 11 Aug 2021 22:09:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 14:55:28

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:43
User entered '04 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:15:46

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:43
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
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 16:15:46

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:43
User entered '04 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:43
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:43
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:43
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:43
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User entered '1'	System	10 Feb 2021 14:56:02

US3182151

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

Form: Unblinding

Generated On: 11 Aug 2021 22:09:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User entered empty.	System	10 Feb 2021 14:56:02

US3182151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:27:24
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:12

US3182151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:27:24
User entered '04 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:12

US3182151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:27:24
User entered '14:59'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:56:12

US3182151

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User entered '04 Feb 2021 14:59'	System	10 Feb 2021 14:56:12

US3182151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:55
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:55:42

US3182151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:55
User entered '04 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:55:42

US3182151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:25:55
User entered '14:45'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:55:42

US3182151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:41
User entered '04 Feb 2021 14:45'	System	10 Feb 2021 14:55:42

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:01

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:31:12
User entered '29 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:03:56

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:01

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:31:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:03:56

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:01

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:31:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:03:56

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:01

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:31:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:03:56

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:01

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:31:12
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:03:56

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:06:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:04:18

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:06:15
User entered '29 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:04:18

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:06:15
User entered 'Urine (URINE)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:04:18

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Oct 2020 12:18:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 20:06:15
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Form will be submitted today, test is confirmed.' (Site from System).	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:05:01
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	29 Sep 2020 19:04:18
User entered 'Positive (POSITIVE)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:04:18

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
Query 'Query Text: Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).		19 Mar 2021 21:03:20
User opened query 'Query Text: Per CDM : Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 17:55:48
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:06:15
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:04:18

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:06:15
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:04:18

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:06:15
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 19:04:18

US3182151

Folder: Unscheduled 29 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:35
User entered empty.	System	29 Sep 2020 19:04:18

US3182151

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:09:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:46
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	05 Feb 2021 02:04:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:09:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:23:54
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:11:29

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:20:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:20:50
Data point term sent to Coder	System	09 Sep 2020 20:19:58
DataPoint Un-verified.	Cassie Uminski (b) (4)	09 Sep 2020 20:19:48
Coding entries removed.	(b) (4) Cassie Uminski (b) (4)	09 Sep 2020 20:19:48
User entered 'MULTIVITAMIN (Unknown)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Sep 2020 20:19:48
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:25:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:14:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:14:17
Data point term sent to Coder	System	11 Aug 2020 19:13:04
User entered 'Multivitamin'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'Health Maintenance'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
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 10:58:17
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	11 Aug 2020 19:12:03
User entered 'un May 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:37:51
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:22
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:19:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Sep 2020 20:19:48
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:37:52
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:22
User entered '27 Sep 2020' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:22
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Sep 2020 20:19:48
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 14:25:01
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	11 Aug 2020 19:12:03
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User entered '1'	System	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User entered '1'	System	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:25
User entered '804 (804)'	System	11 Aug 2020 19:12:03

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:14:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:14:17
Data point term sent to Coder	System	11 Aug 2020 19:13:04
User entered 'Benadryl'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered '25'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
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).	(b) (4), (b) (6)	13 Aug 2020 10:58:25
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	11 Aug 2020 19:12:50
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered '0'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:25:01
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered empty.	System	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered empty.	System	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered empty.	System	11 Aug 2020 19:12:50

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTS YNOM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 21:58:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	23 Dec 2020 21:58:29
Data point term sent to Coder	System	03 Dec 2020 16:27:01
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	03 Dec 2020 16:26:50
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'Please note that the brand is unknown and therefore no further information is available' (Site from System).	Cassie Uminski (b) (4)	03 Dec 2020 16:26:50
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 11:46:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:33
Data point term sent to Coder	System	29 Oct 2020 12:33:57
User entered 'prenatal vitamin (brand unknown)'	Amy Maroun (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:08:07
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).		17 Feb 2021 04:16:40
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:48:48
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:48:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:48:45
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:55:30
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:31
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:35
User entered 'health maintenance'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:29
User entered 'l'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:28
User entered 'tablet (TABLET)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:37
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:25
User entered 'once daily (QD)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:09
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:12
User entered 'Oral (ORAL)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:19
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:06
User entered '28 Sep 2020'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:15
User entered '0'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:04
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:17
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:39:02
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '1'	System	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '1'	System	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '804 (804)'	System	29 Oct 2020 12:33:02

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:24:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	30 Oct 2020 04:24:40
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
Data point term sent to Coder	System	29 Oct 2020 12:34:57
User entered 'B12 vitamin'	Amy Maroun (b) (4)	29 Oct 2020 12:34:11
	(b) (4)	

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:08:00
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate.' (Site from DM).		17 Feb 2021 04:16:58
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:48:58
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:48:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:48:55
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:54:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'health maintenance'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '5000'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'ug (ug)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'once daily (QD)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Oral (ORAL)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '28 Sep 2020'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '0'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '1'	System	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '1'	System	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '804 (804)'	System	29 Oct 2020 12:34:11

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:30:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:30:07
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
Data point term sent to Coder	System	29 Oct 2020 12:34:57
User entered 'folic acid'	Amy Maroun (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:07:51
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).		17 Feb 2021 04:17:09
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:49:11
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:49:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:49:07
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:54:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'health maintenance'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '400'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'ug (ug)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'once daily (QD)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Oral (ORAL)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '28 Sep 2020'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '0'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '1'	System	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '1'	System	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User entered '804 (804)'	System	29 Oct 2020 12:34:45

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:30:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:30:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
Data point term sent to Coder	System	29 Oct 2020 12:35:58
User entered 'tylenol'	Amy Maroun (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 04:17:19
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria' answered with 'Does not meet AE reporting criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:49:22

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 10:55:53
	(b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'headache'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '650'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'mg (mg)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'once daily (QD)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Oral (ORAL)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '06 Aug 2020'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '0'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '06 Aug 2020'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User entered '1'	System	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User entered '1'	System	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:40
User entered '804 (804)'	System	29 Oct 2020 12:35:35

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Feb 2021 14:55:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 14:55:48
Data point term sent to Coder	System	10 Feb 2021 14:54:59
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:54:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:31:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:31:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
Data point term sent to Coder	System	29 Oct 2020 12:37:59
User entered 'Tylenol'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:07:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the JOINT ACHES is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of JOINT ACHES did not meet the AE reporting criteria. ' (Site from DM).		03 Mar 2021 13:57:32
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the JOINT ACHES is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of JOINT ACHES did not meet the AE reporting criteria. ' answered with 'Does not meet AE reporting criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	28 Feb 2021 05:14:21

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the JOINT ACHES is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of JOINT ACHES did not meet the AE reporting criteria. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4)	26 Feb 2021 02:45:24
	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:54:23
User entered 'Joint aches' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:54:23
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	29 Oct 2020 15:40:44
User entered 'headache'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '650'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'mg (mg)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'once daily (QD)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Oral (ORAL)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered empty.	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '10 Aug 2020'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '0'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered '10 Aug 2020'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 04:17:40
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' answered with 'Updated indication per diary' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 14:54:30
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:56:22
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User entered '1'	System	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User entered 'I'	System	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:12:43
User entered '804 (804)'	System	29 Oct 2020 12:37:04

US3182151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:09:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:29:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:41
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	05 Feb 2021 02:04:59

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:01

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:36
User signature succeeded.	Mary Beth Manning	23 Apr 2021 12:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:53:24
User closed query 'Please clarify date as progress note is dated 24Mar2021. At this visit she was staying in the study. ' (Site from CRA).		22 Apr 2021 21:53:21
Query 'Please clarify date as progress note is dated 24Mar2021. At this visit she was staying in the study. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:44:32
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:44:18
User entered '24 Mar 2021' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:44:18
User opened query 'Please clarify date as progress note is dated 24Mar2021. At this visit she was staying in the study. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:36:42
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:18:48
User entered '04 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:08:49

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:01

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:36
DataPoint Verified.		22 Apr 2021 21:53:24
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:48
User entered 'Pregnancy (PREGNANCY)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:08:49

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:01

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 01:55:36
DataPoint Verified.		22 Apr 2021 21:53:24
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:48
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:08:49

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:01

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:36
DataPoint Verified.		07 Apr 2021 17:39:37
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 17:08:49
	(b) (4)	

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:01

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:36
DataPoint Verified.		07 Apr 2021 17:39:29
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:48
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:08:49

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:01

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:36
DataPoint Verified.		07 Apr 2021 17:39:31
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 17:08:49
	(b) (4)	

US3182151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:01

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:36
DataPoint Verified.		07 Apr 2021 17:39:33
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 17:08:49
	(b) (4)	