

US3182236 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:37:20

All time stamps listed in this document are displayed in GMT

US3182236

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

[Participant ID](#)

US3182236

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

US3182236

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Date of Informed Consent (*dd MMM yyyy*) 7 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

US3182236

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3182236

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Were any significant conditions reported?

Yes ☒

No ☐

US3182236

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3182236

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	ALLERGY TO DIFLUCAN
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

US3182236

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	ALLERGY TO SEAFOOD
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

US3182236

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	BILATERAL HYPEROPIA
Start date (dd MMM yyyy)	UN UNK 1967
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 1967
Start Year (derived)	1967
Stop Month and Year (derived)	
Stop Year (derived)	

US3182236

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	OSTEOARTHRITIS-BACK/ BILATERAL FEET/ BILATERAL KNEES/ BILATERAL ELBOWS/ BILATERAL SHOULDERS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	FRACTURED NOSE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	RHINOPLASTY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3182236

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	BLOCKED SINUSES
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3182236

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Condition	SINUPLASTY
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3182236

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:04 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 15:04
Height (<i>xxx.x</i>)	161.5 cm
Weight (<i>xxx.x</i>)	93.3 kg
BMI (<i>xxx.x</i>)	35.77145 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

Date of assessment (dd MMM yyyy) 07 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

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

CURRENTLY LOOKING FOR
PART TIME WORK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:45:26

Generated On: 09 Jun 2021 15:37:20

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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

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

What was the participant's randomization number? 102117

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Height	ND - Not Done
Weight	ND - Not Done

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	15:04 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 15:04
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 16:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 7 AUG 2020

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

Treatment Date and Time (derived) 7 AUG 2020 15:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 AUG 2020
Collection time (00:00-23:59)	15:25 (24 HR)
Collection date and time (derived)	07 AUG 2020 15:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:18	07 AUG 2020 15:18
Nasopharyngeal Swab 2	No		

US3182236

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 16:16

PC Open Date & Time

07 AUG 2020 16:05

PC Close Date & Time

07 AUG 2020 18:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 96.6 °F

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

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

PC Time Stamp	07 AUG 2020 21:17
PC Open Date & Time	07 AUG 2020 19:30
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

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

95.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 06:26

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

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

98.0 °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

09 AUG 2020 15:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

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

10 AUG 2020 19:59

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 19:40

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

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

95.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 05:58

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

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

13 AUG 2020 14:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 16:17

PC Open Date & Time

07 AUG 2020 16:05

PC Close Date & Time

07 AUG 2020 18:35

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 21:18

PC Open Date & Time

07 AUG 2020 19:30

PC Close Date & Time

08 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 06:17

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 15:18

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 19:59

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 19:38

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 05:57

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 14:07

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 ☐

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 16:18
PC Open Date & Time	07 AUG 2020 16:05
PC Close Date & Time	07 AUG 2020 18:35

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 ☐

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 21:17
PC Open Date & Time	07 AUG 2020 19:30
PC Close Date & Time	08 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 06:17
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

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)

55 of 2134

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 15:18
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 ☒

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:58
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

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

59 of 2134

EAB) (1725)

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 19:38
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

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

61 of 2134

EAB) (1725)

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 05:57
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 ☒

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 14:07
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3182236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:19 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:19
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:46
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3182236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 SEP 2020

What was the treatment time? (00:00-23:59) 13:09 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 13:09

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

US3182236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

13:04 (24 HR)

Collection date and time (derived)

10 SEP 2020 13:04

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	10 SEP 2020 12:25
Nasopharyngeal Swab 2	No		

US3182236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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

10 SEP 2020 13:43

PC Open Date & Time

10 SEP 2020 13:29

PC Close Date & Time

10 SEP 2020 15:59

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	10 SEP 2020 21:12
PC Open Date & Time	10 SEP 2020 16:54
PC Close Date & Time	11 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

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

96.2 °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

12 SEP 2020 06:39

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

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

94.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 20:08

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:19

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

15 SEP 2020 21:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:45

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 13:44

PC Open Date & Time

10 SEP 2020 13:29

PC Close Date & Time

10 SEP 2020 15:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:13

PC Open Date & Time

10 SEP 2020 16:54

PC Close Date & Time

11 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 06:33

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:24

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 18:18

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:00

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 20:44

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 ☐

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 13:44
PC Open Date & Time	10 SEP 2020 13:29
PC Close Date & Time	10 SEP 2020 15:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 ☐

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:14
PC Open Date & Time	10 SEP 2020 16:54
PC Close Date & Time	11 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

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 ☒

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 06:33
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

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 ☒

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:23
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 ☒

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:05
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

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 ☒

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:18
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

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 ☒

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EAB) (1725)

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US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:00
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 ☒

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:43
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3182236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:24:56

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 13:57
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

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.

US3182236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 OCT 2020

Collection time (00:00-23:59)

14:06 (24 HR)

Collection date and time (derived)

08 OCT 2020 14:06

US3182236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:19:42

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

08 OCT 2020 14:24:40

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 15:49:31

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 13:57:09

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 20:54:14

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 15:33:29

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

Patient Cloud Open Date & Time	20 DEC 2020 00:01
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Patient Cloud Close Date & Time	24 DEC 2020 23:59
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US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

27 DEC 2020 11:48:14

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

05 JAN 2021 17:32:01

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 JAN 2021 18:01:34
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 JAN 2021 12:00:58
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 FEB 2021 18:32:06
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

Date and time of submission	
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 FEB 2021 17:35:21
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 15:45:53

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 215

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 15:54:16

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 MAR 2021 12:33:07
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 14:20:34

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 MAY 2021 00:01
Patient Cloud Close Date & Time	20 MAY 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 460

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

Patient Cloud Open Date & Time	14 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	21 AUG 2022 00:01
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Patient Cloud Close Date & Time	25 AUG 2022 23:59
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US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3182236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:37:20

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		19 MAR 2021 14:33:22

US3182236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	23 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 14:56:23

Generated On: 09 Jun 2021 15:37:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:10
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3182236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 14:56:23

Generated On: 09 Jun 2021 15:37:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	23 FEB 2021
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Collection time (00:00-23:59)	09:21 (24 HR)
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Collection date and time (derived)	23 FEB 2021 09:21
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US3182236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact Contact Made ☐
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182236

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:37:20

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"/>

US3182236

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:37:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	23 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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US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 10 Apr 2021 21:25:36

Generated On: 09 Jun 2021 15:37:20

Date of updated informed consent (<i>dd MMM yyyy</i>)	23 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>)	23 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 checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Height	163.0 cm
Weight	81.5 kg
BMI (xxx.x)	30.67485

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Height	163.0 cm
Weight	81.5 kg
BMI (xxx.x)	30.67485
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)	23 FEB 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:10
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Height	163.0 cm
Weight	81.5 kg
BMI (xxx.x)	30.67485
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)	23 FEB 2021
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 09:36 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 09:36

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

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

09:21 (24 HR)

Collection date and time (derived)

23 FEB 2021 09:21

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00 - 23:59)

09:15

Collection Date and Time (derived)

23 FEB 2021 09:15

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:41:39

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 17:04:45

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 17:04:45

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3182236

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 14:56:23

Generated On: 09 Jun 2021 15:37:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 14:56:23

Generated On: 09 Jun 2021 15:37:20

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)	24 MAR 2021
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 14:51
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 14:56:23

Generated On: 09 Jun 2021 15:37:20

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)	24 MAR 2021
Time of assessment (00:00-23:59)	15:26 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 15:26
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3182236

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 14:56:23

Generated On: 09 Jun 2021 15:37:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3182236

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 14:56:22

Generated On: 09 Jun 2021 15:37:20

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 MAR 2021

What was the treatment time? (00:00-23:59) 14:56 (24 HR)

Treatment Date and Time (derived) 24 MAR 2021 14:56

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

US3182236

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 14:56:22

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 15:50:17

Generated On: 09 Jun 2021 15:37:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:50:17

Generated On: 09 Jun 2021 15:37:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182236

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:11:18

Generated On: 09 Jun 2021 15:37:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:11:18

Generated On: 09 Jun 2021 15:37:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	21 APR 2021 10:00
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182236

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:11:18

Generated On: 09 Jun 2021 15:37:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3182236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:11:18

Generated On: 09 Jun 2021 15:37:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 APR 2021

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

21 APR 2021 10:20

US3182236

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 30 Mar 2021 14:56:22

Generated On: 09 Jun 2021 15:37:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

AEID	USA-US075-2021-MRNA-1273-P30 1000012
Adverse event	WORSENING OF LEFT KNEE OSTEOARTHRITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	19 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT PRESENTED TO SITE FOR FOLLOW UP VISIT, SUBJECT CONFIRMED HAVING A LEFT KNEE REPLACEMENT SURGERY ON 1/18/2021. MEDICAL RECORDS RELEASE SENT TO SUBJECT TO OBTAIN MEDICAL RECORDS.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Name of Medication CORTISONE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS-BACK/
BILATERAL FEET/ BILATERAL
KNEES/ BILATERAL ELBOWS/
BILATERAL SHOULDERS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify YEARLY

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

	Transdermal	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRAARTICULAR	
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

6 TIMES PER WEEK

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

	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 1995	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

	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 2016	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Name of Medication IRON

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 60

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

	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 1997	
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"/>

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Name of Medication BIOTIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 3

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE FOR
STOMACH PROTECTION

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Mar 2021 04:41:38

Generated On: 09 Jun 2021 15:37:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>

US3182236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 10 Mar 2021 21:48:36

Generated On: 09 Jun 2021 15:37:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3182236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 10 Apr 2021 21:25:36

Generated On: 09 Jun 2021 15:37:20

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 JAN 2021	TOTAL LEFT KNEE REPLACEMENT	Adverse Event	

US3182236

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:37:20

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 21 Apr 2021 11:55:08

Generated On: 09 Jun 2021 15:37:20

SAEID	USA-US075-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Apr 2021 11:55:08

Generated On: 09 Jun 2021 15:37:20

SAEID	USA-US075-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/MAR/2021 12:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Apr 2021 11:55:08

Generated On: 09 Jun 2021 15:37:20

SAEID	USA-US075-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/APR/2021 13:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Apr 2021 11:55:08

Generated On: 09 Jun 2021 15:37:20

SAEID	USA-US075-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/APR/2021 08:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3182236 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182236

Form: Participant Creation

Generated On: 09 Jun 2021 15:37:20

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Aug 2020 21:21:53
User entered 'US3182236'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:14:22

US3182236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:40
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:00

US3182236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:40
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:14:23

US3182236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:40
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:00

US3182236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'SCRN'	System	07 Aug 2020 19:50:00

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:14:24

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '60'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'YEARS'	System	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '60'	System	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered 'Female (F)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:37:20

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:05:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:53:21

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:06
User entered '7 Aug 2020'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Aug 2020'	System	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2020'	System	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:06
User entered 'Amendment 1 (1)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:06
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:06
User entered empty.	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:06
User entered empty.	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:06
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:15

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:14:23

US3182236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:37:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'I'	System	07 Aug 2020 19:50:21

US3182236

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:37:20

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:38
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:21

US3182236

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:37:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:06:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:53

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:09:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:09:14
Data point term sent to Coder	System	17 Aug 2020 15:07:56
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 1995'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 1995'	System	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '1995'	System	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:07

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:15:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:15:16
Data point term sent to Coder	System	17 Aug 2020 15:07:57
User entered 'Allergy to Diflucan'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 1989'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 1989'	System	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '1989'	System	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:23

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Seafood allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:18:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:18:15
Data point term sent to Coder	System	17 Aug 2020 15:07:57
User entered 'Allergy to seafood'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 1977'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 1977'	System	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '1977'	System	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:39

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:54
User closed query 'Per DM CLR: Please specify the eye laterality with HYPEROPIA. Review and update Med History eCRF as appropriate. ' (Site from DM).		29 Sep 2020 02:26:15
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 19:21:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 19:21:49
Query 'Per DM CLR: Please specify the eye laterality with HYPEROPIA. Review and update Med History eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:20:53
Data point term sent to Coder	System	21 Sep 2020 19:20:51
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:20:49
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:20:49
User entered 'Bilateral HYPEROPIA' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:20:49
User opened query 'Per DM CLR: Please specify the eye laterality with HYPEROPIA. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:25:01
DataPoint Verified.		21 Aug 2020 15:58:12
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:10:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:10:18
Data point term sent to Coder	System	17 Aug 2020 15:08:59
User entered 'Hyperopia'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 1967'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 1967'	System	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '1967'	System	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:07:58

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:10:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:10:18
Data point term sent to Coder	System	17 Aug 2020 15:08:59
User entered 'Hypothyroidism'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2008'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2008'	System	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2008'	System	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:08:14

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:08:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:08:56
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:03
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).		29 Sep 2020 02:26:26
Data point term sent to Coder	System	21 Sep 2020 19:21:59
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4)	21 Sep 2020 19:21:46
DataPoint Un-verified.	(b) (4)	
	Cassie Uminski (b) (4)	21 Sep 2020 19:21:42
Coding entries removed.	(b) (4)	
	Cassie Uminski (b) (4)	21 Sep 2020 19:21:42
User entered 'OSTEOARTHRITIS-Back/ bilateral feet/ bilateral knees/ bilateral elbows/ bilateral shoulders' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	Cassie Uminski (b) (4)	21 Sep 2020 19:21:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 06:25:18
		21 Aug 2020 15:58:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 15:10:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	17 Aug 2020 15:10:17
User entered 'Osteoarthritis'	System	17 Aug 2020 15:09:00
	Cassie Uminski (b) (4)	17 Aug 2020 15:08:28
	(b) (4)	

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2016'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2016'	System	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2016'	System	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered empty.	System	17 Aug 2020 15:08:28

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:14:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:14:09
Data point term sent to Coder	System	17 Aug 2020 15:09:01
User entered 'Blood Clot-Right Foot'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2010'	System	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2010'	System	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2010'	System	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2010'	System	17 Aug 2020 15:08:59

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Fractured nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:11:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:11:08
Data point term sent to Coder	System	17 Aug 2020 15:10:05
User entered 'Fractured Nose'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2001'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2001'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2001'	System	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2001'	System	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2001'	System	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2001'	System	17 Aug 2020 15:09:13

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Rhinoplasty, LLT: Rhinoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:11:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:11:08
Data point term sent to Coder	System	17 Aug 2020 15:10:06
User entered 'Rhinoplasty'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:28

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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2001'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2001'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2001'	System	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2001'	System	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2001'	System	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2001'	System	17 Aug 2020 15:09:28

US3182236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 10:15:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 10:15:22
Data point term sent to Coder	System	17 Aug 2020 15:10:06
User entered 'Blocked Sinuses'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:58

US3182236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2012'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:58

US3182236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:58

US3182236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:58

US3182236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2012'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:58

US3182236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:09:58

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2012'	System	17 Aug 2020 15:09:58

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2012'	System	17 Aug 2020 15:09:58

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2012'	System	17 Aug 2020 15:09:58

US3182236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2012'	System	17 Aug 2020 15:09:58

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinuplasty, LLT: Sinuplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:12:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:12:11
Data point term sent to Coder	System	17 Aug 2020 15:11:10
User entered 'Sinuplasty'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2012'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered 'un UNK 2012'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:58:12
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2012'	System	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2012'	System	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'Jan 2012'	System	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:37:20

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '2012'	System	17 Aug 2020 15:10:09

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered '15:04'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered '07 Aug 2020 15:04'	System	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered '161.5' cm	Cassie Uminski (b) (4)	17 Aug 2020 14:54:01
DataPoint set to visible.	(b) (4) System	07 Aug 2020 19:50:21

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered '93.3' kg	Cassie Uminski (b) (4)	17 Aug 2020 14:54:01
DataPoint set to visible.	(b) (4) System	07 Aug 2020 19:50:21

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
Amendment Manager: User entered '35.77145'	System	16 Sep 2020 23:48:01
User entered '35.8'	System	17 Aug 2020 14:54:01
DataPoint set to visible.	System	07 Aug 2020 19:50:21

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'kg/m2'	System	17 Aug 2020 14:54:01
DataPoint set to visible.	System	07 Aug 2020 19:50:21

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 02:42:50
DataPoint Verified.		24 Sep 2020 12:12:41
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)	21 Sep 2020 19:20:13
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:20:08
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:20:08
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 05:48:02
DataPoint Verified.		21 Aug 2020 16:07:15
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 12:12:44
DataPoint Un-verified.	Cassie Uminski (b) (4)	21 Sep 2020 19:20:08
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	21 Sep 2020 19:20:08
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'bpm'	System	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'breaths/min'	System	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'mmHg'	System	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:15
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User entered 'mmHg'	System	17 Aug 2020 14:54:01

US3182236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26

US3182236

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:35
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:34

US3182236

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:07:35
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:34

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:37:20

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:08:23
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:58

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'Currently looking for part time work'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
User entered '0'	(b) (4)	17 Aug 2020 15:06:41
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
User entered '0'	(b) (4)	17 Aug 2020 15:06:41
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:37:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:05:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:45:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:20
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:06:41

US3182236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:34
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:36

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:34
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:36

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

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 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:34
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:36

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'VISIT1'	System	17 Aug 2020 15:05:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:39:21

US3182236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:58:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:58:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 19:39:21
User entered '102117' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:39:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:39:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

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 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

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 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:18

US3182236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:18

US3182236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:37:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:18

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '15:04'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '07 Aug 2020 15:04'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '98.6' F	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '64'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'bpm'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '16'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'breaths/min'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '130'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '86'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:58:11
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).		17 Aug 2020 15:03:23
User entered '16:20'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '07 Aug 2020 16:20'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '98.1' F	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '80'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'bpm'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '14'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'breaths/min'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '119'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:09:52
User entered '81'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	17 Aug 2020 15:03:23

US3182236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:14
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:42

US3182236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:14
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:04:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:34
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	07 Aug 2020 19:50:54
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	07 Aug 2020 19:50:54
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	07 Aug 2020 19:50:42
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:34
User entered empty.	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

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 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:34
User entered empty.	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:34
User entered '7 Aug 2020'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:34
User entered '15:45' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:54
User entered empty.	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered '7 Aug 2020 15:45'	System	07 Aug 2020 19:50:54
User entered empty.	System	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:34
User entered 'Left Arm (LEFT ARM)'	Amy Maroun (b) (4) (b) (4)	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 16:11:34
User entered 'ONCE'	System	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 19:50:42

US3182236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:12

US3182236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:45
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:12

US3182236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:45
User entered '15:25'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:12

US3182236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered '07 Aug 2020 15:25'	System	17 Aug 2020 15:05:12

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:58
User entered '07 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	17 Aug 2020 15:05:02
	(b) (4)	

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:58
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:58
User entered '15:18'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered '07 Aug 2020 15:18'	System	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:58
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:11:58
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered empty.	System	17 Aug 2020 15:05:02

US3182236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:46:05
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:05:21

US3182236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	17 Aug 2020 15:05:21

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:16:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '360da9e1-3036-4ff9-b179-1580613245ce' User entered 'Yes (Y)'	System	07 Aug 2020 20:16:35
	System	07 Aug 2020 20:16:35

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:16:05', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '360da9e1-3036-4ff9-b179-1580613245ce' User entered '98.1'	System	07 Aug 2020 20:16:35
	System	07 Aug 2020 20:16:35

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:16:19', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '360da9e1-3036-4ff9-b179-1580613245ce'	System	07 Aug 2020 20:16:35
User entered 'No (N)'	System	07 Aug 2020 20:16:35

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:16:31', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '360da9e1-3036-4ff9-b179-1580613245ce' User entered '07 Aug 2020 16:16'	System	07 Aug 2020 20:16:35
	System	07 Aug 2020 20:16:35

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 16:05'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 18:35'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:16:51', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e35e8920-7042-43e4-bb89-32beda941e80' User entered 'Yes (Y)'	System	08 Aug 2020 01:17:10
	System	08 Aug 2020 01:17:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:16:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e35e8920-7042-43e4-bb89-32beda941e80' User entered '96.6'	System	08 Aug 2020 01:17:10
	System	08 Aug 2020 01:17:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e35e8920-7042-43e4-bb89-32beda941e80'	System	08 Aug 2020 01:17:10
User entered 'No (N)'	System	08 Aug 2020 01:17:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e35e8920-7042-43e4-bb89-32beda941e80' User entered '07 Aug 2020 21:17'	System	08 Aug 2020 01:17:10
	System	08 Aug 2020 01:17:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 19:30'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 2'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:26:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e48f9f09-7a9e-4380-a43d-3e103df65265'	System	09 Aug 2020 10:26:34
User entered 'Yes (Y)'	System	09 Aug 2020 10:26:34

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:26:16', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e48f9f09-7a9e-4380-a43d-3e103df65265' User entered '95.2'	System	09 Aug 2020 10:26:34
	System	09 Aug 2020 10:26:34

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:26:23', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e48f9f09-7a9e-4380-a43d-3e103df65265'	System	09 Aug 2020 10:26:34
User entered 'No (N)'	System	09 Aug 2020 10:26:34

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:26:31', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'e48f9f09-7a9e-4380-a43d-3e103df65265'	System	09 Aug 2020 10:26:34
User entered '09 Aug 2020 06:26'	System	09 Aug 2020 10:26:34

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 3'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:41', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0acb2ab6-a605-4344-8664-c73dc3e098cc' User entered 'Yes (Y)'	System	09 Aug 2020 19:20:05
	System	09 Aug 2020 19:20:05

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:19:55', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0acb2ab6-a605-4344-8664-c73dc3e098cc' User entered '98.0'	System	09 Aug 2020 19:20:05
	System	09 Aug 2020 19:20:05

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:20:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0acb2ab6-a605-4344-8664-c73dc3e098cc' User entered 'No (N)'	System	09 Aug 2020 19:20:05
	System	09 Aug 2020 19:20:05

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:20:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0acb2ab6-a605-4344-8664-c73dc3e098cc' User entered '09 Aug 2020 15:20'	System	09 Aug 2020 19:20:05
	System	09 Aug 2020 19:20:05

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 4'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:36', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b10e3c68-c348-4cd0-91b8-3308c034e09e' User entered 'Yes (Y)'	System	10 Aug 2020 23:59:51
	System	10 Aug 2020 23:59:51

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b10e3c68-c348-4cd0-91b8-3308c034e09e' User entered '97.6'	System	10 Aug 2020 23:59:51
	System	10 Aug 2020 23:59:51

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b10e3c68-c348-4cd0-91b8-3308c034e09e'	System	10 Aug 2020 23:59:51
User entered 'No (N)'	System	10 Aug 2020 23:59:51

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:50', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b10e3c68-c348-4cd0-91b8-3308c034e09e' User entered '10 Aug 2020 19:59'	System	10 Aug 2020 23:59:51
	System	10 Aug 2020 23:59:51

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 5'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:39', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f6b85f45-9834-4252-a780-08525f8f6f17'	System	11 Aug 2020 23:40:10
User entered 'Yes (Y)'	System	11 Aug 2020 23:40:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:39:57', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f6b85f45-9834-4252-a780-08525f8f6f17' User entered '97.9'	System	11 Aug 2020 23:40:10
	System	11 Aug 2020 23:40:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:40:01', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f6b85f45-9834-4252-a780-08525f8f6f17'	System	11 Aug 2020 23:40:10
User entered 'No (N)'	System	11 Aug 2020 23:40:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:40:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f6b85f45-9834-4252-a780-08525f8f6f17'	System	11 Aug 2020 23:40:10
User entered '11 Aug 2020 19:40'	System	11 Aug 2020 23:40:10

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 6'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:34', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24def1d9-2dba-4728-97e8-04c0d8a290e8' User entered 'Yes (Y)'	System	13 Aug 2020 09:58:13
	System	13 Aug 2020 09:58:13

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:58:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24def1d9-2dba-4728-97e8-04c0d8a290e8' User entered '95.3'	System	13 Aug 2020 09:58:13
	System	13 Aug 2020 09:58:13

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:58:05', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24def1d9-2dba-4728-97e8-04c0d8a290e8' User entered 'No (N)'	System	13 Aug 2020 09:58:13
	System	13 Aug 2020 09:58:13

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:58:09', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24def1d9-2dba-4728-97e8-04c0d8a290e8' User entered '13 Aug 2020 05:58'	System	13 Aug 2020 09:58:13
	System	13 Aug 2020 09:58:13

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 7'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:46', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4ebbdcd3-5cd2-4ef3-9dae-d6f98cdee1d0' User entered 'Yes (Y)'	System	13 Aug 2020 18:08:25
	System	13 Aug 2020 18:08:25

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:08:12', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4ebbdcd3-5cd2-4ef3-9dae-d6f98cdee1d0' User entered '98.5'	System	13 Aug 2020 18:08:25
	System	13 Aug 2020 18:08:25

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:08:17', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4ebbdcd3-5cd2-4ef3-9dae-d6f98cdee1d0'	System	13 Aug 2020 18:08:25
User entered 'No (N)'	System	13 Aug 2020 18:08:25

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:08:20', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4ebbdcd3-5cd2-4ef3-9dae-d6f98cdee1d0' User entered '13 Aug 2020 14:08'	System	13 Aug 2020 18:08:25
	System	13 Aug 2020 18:08:25

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:17:22', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '080d00ac-7420-4d24-a536-ab268e019320' User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 20:17:54
	System	07 Aug 2020 20:17:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:17:28', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '080d00ac-7420-4d24-a536-ab268e019320' User entered 'No (N)'	System	07 Aug 2020 20:17:54
	System	07 Aug 2020 20:17:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:17:31', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '080d00ac-7420-4d24-a536-ab268e019320' User entered 'No (N)'	System	07 Aug 2020 20:17:54
	System	07 Aug 2020 20:17:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:17:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '080d00ac-7420-4d24-a536-ab268e019320'	System	07 Aug 2020 20:17:54
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 20:17:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:17:52', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '080d00ac-7420-4d24-a536-ab268e019320' User entered '07 Aug 2020 16:17'	System	07 Aug 2020 20:17:54
	System	07 Aug 2020 20:17:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 16:05'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 18:35'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:18:01', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4bb4c267-94a7-4eb3-85dc-c70c21702427'	System	08 Aug 2020 01:18:27
User entered 'None (1)'	System	08 Aug 2020 01:18:27

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:18:04', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4bb4c267-94a7-4eb3-85dc-c70c21702427' User entered 'No (N)'	System	08 Aug 2020 01:18:27
	System	08 Aug 2020 01:18:27

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:18:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4bb4c267-94a7-4eb3-85dc-c70c21702427' User entered 'No (N)'	System	08 Aug 2020 01:18:27
	System	08 Aug 2020 01:18:27

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:18:21', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4bb4c267-94a7-4eb3-85dc-c70c21702427'	System	08 Aug 2020 01:18:27
User entered 'None (1)'	System	08 Aug 2020 01:18:27

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:18:25', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4bb4c267-94a7-4eb3-85dc-c70c21702427' User entered '07 Aug 2020 21:18'	System	08 Aug 2020 01:18:27
	System	08 Aug 2020 01:18:27

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 19:30'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 2'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:35', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07ab9f36-02ac-41a8-9bc7-2536963100f9' User entered 'None (1)'	System	09 Aug 2020 10:17:57
	System	09 Aug 2020 10:17:57

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:39', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07ab9f36-02ac-41a8-9bc7-2536963100f9' User entered 'No (N)'	System	09 Aug 2020 10:17:57
	System	09 Aug 2020 10:17:57

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:42', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07ab9f36-02ac-41a8-9bc7-2536963100f9' User entered 'No (N)'	System	09 Aug 2020 10:17:57
	System	09 Aug 2020 10:17:57

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:48', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07ab9f36-02ac-41a8-9bc7-2536963100f9' User entered 'None (1)'	System	09 Aug 2020 10:17:57
	System	09 Aug 2020 10:17:57

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07ab9f36-02ac-41a8-9bc7-2536963100f9' User entered '09 Aug 2020 06:17'	System	09 Aug 2020 10:17:57
	System	09 Aug 2020 10:17:57

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 3'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:17:51', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '603e2f15-c656-416c-89b6-6ba52cbfbc54'	System	09 Aug 2020 19:18:07
User entered 'None (1)'	System	09 Aug 2020 19:18:07

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:17:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '603e2f15-c656-416c-89b6-6ba52cbfbc54' User entered 'No (N)'	System	09 Aug 2020 19:18:07
	System	09 Aug 2020 19:18:07

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:17:57', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '603e2f15-c656-416c-89b6-6ba52cbfbc54' User entered 'No (N)'	System	09 Aug 2020 19:18:07
	System	09 Aug 2020 19:18:07

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '603e2f15-c656-416c-89b6-6ba52cbfbc54'	System	09 Aug 2020 19:18:07
User entered 'None (1)'	System	09 Aug 2020 19:18:07

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '603e2f15-c656-416c-89b6-6ba52cbfbc54' User entered '09 Aug 2020 15:18'	System	09 Aug 2020 19:18:07
	System	09 Aug 2020 19:18:07

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 4'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:58', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4d7406b7-99bd-4726-94a8-91a4c13bcffc' User entered 'None (1)'	System	10 Aug 2020 23:59:14
	System	10 Aug 2020 23:59:14

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:01', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4d7406b7-99bd-4726-94a8-91a4c13bcffc'	System	10 Aug 2020 23:59:14
User entered 'No (N)'	System	10 Aug 2020 23:59:14

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4d7406b7-99bd-4726-94a8-91a4c13bcffc' User entered 'No (N)'	System	10 Aug 2020 23:59:14
	System	10 Aug 2020 23:59:14

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:06', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4d7406b7-99bd-4726-94a8-91a4c13bcffc' User entered 'None (1)'	System	10 Aug 2020 23:59:14
	System	10 Aug 2020 23:59:14

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:59:10', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '4d7406b7-99bd-4726-94a8-91a4c13bcffc' User entered '10 Aug 2020 19:59'	System	10 Aug 2020 23:59:14
	System	10 Aug 2020 23:59:14

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 5'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:19', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'efcaedf6-379c-4f7f-90f4-bd35fed204ef' User entered 'None (1)'	System	11 Aug 2020 23:38:34
	System	11 Aug 2020 23:38:34

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:22', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'efcaedf6-379c-4f7f-90f4-bd35fed204ef' User entered 'No (N)'	System	11 Aug 2020 23:38:34
	System	11 Aug 2020 23:38:34

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:25', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'efcaedf6-379c-4f7f-90f4-bd35fed204ef' User entered 'No (N)'	System	11 Aug 2020 23:38:34
	System	11 Aug 2020 23:38:34

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:28', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'efcaedf6-379c-4f7f-90f4-bd35fed204ef' User entered 'None (1)'	System	11 Aug 2020 23:38:34
	System	11 Aug 2020 23:38:34

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:31', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'efcaedf6-379c-4f7f-90f4-bd35fed204ef' User entered '11 Aug 2020 19:38'	System	11 Aug 2020 23:38:34
	System	11 Aug 2020 23:38:34

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 6'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:13', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '86d4470c-d1b2-413a-84df-45eb3e482eda' User entered 'None (1)'	System	13 Aug 2020 09:57:29
	System	13 Aug 2020 09:57:29

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:17', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '86d4470c-d1b2-413a-84df-45eb3e482eda' User entered 'No (N)'	System	13 Aug 2020 09:57:29
	System	13 Aug 2020 09:57:29

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:20', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '86d4470c-d1b2-413a-84df-45eb3e482eda' User entered 'No (N)'	System	13 Aug 2020 09:57:29
	System	13 Aug 2020 09:57:29

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:24', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '86d4470c-d1b2-413a-84df-45eb3e482eda' User entered 'None (1)'	System	13 Aug 2020 09:57:29
	System	13 Aug 2020 09:57:29

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:27', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '86d4470c-d1b2-413a-84df-45eb3e482eda' User entered '13 Aug 2020 05:57'	System	13 Aug 2020 09:57:29
	System	13 Aug 2020 09:57:29

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 7'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:27', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'db4bb333-c3e7-4c3a-974c-8a7546f7baee'	System	13 Aug 2020 18:07:43
User entered 'None (1)'	System	13 Aug 2020 18:07:43

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:31', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'db4bb333-c3e7-4c3a-974c-8a7546f7baee' User entered 'No (N)'	System	13 Aug 2020 18:07:43
	System	13 Aug 2020 18:07:43

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:34', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'db4bb333-c3e7-4c3a-974c-8a7546f7baee' User entered 'No (N)'	System	13 Aug 2020 18:07:43
	System	13 Aug 2020 18:07:43

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:36', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'db4bb333-c3e7-4c3a-974c-8a7546f7baee' User entered 'None (1)'	System	13 Aug 2020 18:07:43
	System	13 Aug 2020 18:07:43

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:40', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'db4bb333-c3e7-4c3a-974c-8a7546f7baee' User entered '13 Aug 2020 14:07'	System	13 Aug 2020 18:07:43
	System	13 Aug 2020 18:07:43

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:17:59', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3'	System	07 Aug 2020 20:18:49
User entered 'No interference with activity (1)'	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:18:15', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3' User entered 'None (0)'	System	07 Aug 2020 20:18:49
	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:18:21', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3' User entered 'None (0)'	System	07 Aug 2020 20:18:49
	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:18:25', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3' User entered 'None (0)'	System	07 Aug 2020 20:18:49
	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:18:28', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3' User entered 'None (0)'	System	07 Aug 2020 20:18:49
	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:18:30', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3' User entered 'None (0)'	System	07 Aug 2020 20:18:49
	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:18:36', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3' User entered 'No (N)'	System	07 Aug 2020 20:18:49
	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T16:18:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '16455a29-5fa4-4576-a285-b7bda03453b3' User entered '07 Aug 2020 16:18'	System	07 Aug 2020 20:18:49
	System	07 Aug 2020 20:18:49

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 16:05'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 18:35'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:19', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5' User entered 'None (0)'	System	08 Aug 2020 01:18:00
	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:26', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5'	System	08 Aug 2020 01:18:00
User entered 'No interference with activity (1)'	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:34', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5' User entered 'None (0)'	System	08 Aug 2020 01:18:00
	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:37', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5' User entered 'None (0)'	System	08 Aug 2020 01:18:00
	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:40', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5' User entered 'None (0)'	System	08 Aug 2020 01:18:00
	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:43', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5' User entered 'None (0)'	System	08 Aug 2020 01:18:00
	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5' User entered 'No (N)'	System	08 Aug 2020 01:18:00
	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-07T21:17:55', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'da3679de-2ab3-47f1-ab3d-7e9087c68fd5' User entered '07 Aug 2020 21:17'	System	08 Aug 2020 01:18:00
	System	08 Aug 2020 01:18:00

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '07 Aug 2020 19:30'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 2'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:16:43', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05' User entered 'None (0)'	System	09 Aug 2020 10:17:27
	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:16:48', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05' User entered 'None (0)'	System	09 Aug 2020 10:17:27
	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:16:55', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05' User entered 'None (0)'	System	09 Aug 2020 10:17:27
	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:16:58', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05' User entered 'None (0)'	System	09 Aug 2020 10:17:27
	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05' User entered 'None (0)'	System	09 Aug 2020 10:17:27
	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05' User entered 'None (0)'	System	09 Aug 2020 10:17:27
	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:10', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05'	System	09 Aug 2020 10:17:27
User entered 'No (N)'	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T06:17:24', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '24bd8e92-725f-475e-b3f9-7cebb90d0a05' User entered '09 Aug 2020 06:17'	System	09 Aug 2020 10:17:27
	System	09 Aug 2020 10:17:27

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 3'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered 'None (0)'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:11', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered 'None (0)'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:15', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered 'None (0)'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:18', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered 'None (0)'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:21', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered 'None (0)'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:23', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered 'None (0)'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:26', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered 'No (N)'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-09T15:18:30', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9ba2f507-7ea8-4ad3-a4ea-760b4c6c052a' User entered '09 Aug 2020 15:18'	System	09 Aug 2020 19:18:33
	System	09 Aug 2020 19:18:33

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 4'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:32', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered 'None (0)'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:34', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered 'None (0)'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:37', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered 'None (0)'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:39', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered 'None (0)'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:41', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered 'None (0)'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:43', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered 'None (0)'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:46', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered 'No (N)'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-10T19:58:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bc32f7a1-6a87-4fe0-952d-012647a645ff' User entered '10 Aug 2020 19:58'	System	10 Aug 2020 23:58:58
	System	10 Aug 2020 23:58:58

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 5'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:37:45', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676' User entered 'None (0)'	System	11 Aug 2020 23:38:12
	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:37:48', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676' User entered 'None (0)'	System	11 Aug 2020 23:38:12
	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:37:51', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676' User entered 'None (0)'	System	11 Aug 2020 23:38:12
	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:37:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676' User entered 'None (0)'	System	11 Aug 2020 23:38:12
	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:37:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676' User entered 'None (0)'	System	11 Aug 2020 23:38:12
	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:37:58', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676' User entered 'None (0)'	System	11 Aug 2020 23:38:12
	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676'	System	11 Aug 2020 23:38:12
User entered 'No (N)'	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-11T19:38:10', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3c67879a-71f5-4e0f-9ee1-0ddac4a60676' User entered '11 Aug 2020 19:38'	System	11 Aug 2020 23:38:12
	System	11 Aug 2020 23:38:12

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 6'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:56:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered 'None (0)'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:56:51', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered 'None (0)'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:56:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered 'None (0)'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:56:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered 'None (0)'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:56:58', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered 'None (0)'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:01', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered 'None (0)'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered 'No (N)'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T05:57:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '63d7eb36-b93e-4754-a9ee-5a3401de2308' User entered '13 Aug 2020 05:57'	System	13 Aug 2020 09:57:13
	System	13 Aug 2020 09:57:13

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 7'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76' User entered 'None (0)'	System	13 Aug 2020 18:07:26
	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:04', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76' User entered 'None (0)'	System	13 Aug 2020 18:07:26
	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:06', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76' User entered 'None (0)'	System	13 Aug 2020 18:07:26
	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76' User entered 'None (0)'	System	13 Aug 2020 18:07:26
	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:10', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76' User entered 'None (0)'	System	13 Aug 2020 18:07:26
	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:12', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76' User entered 'None (0)'	System	13 Aug 2020 18:07:26
	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:20', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76'	System	13 Aug 2020 18:07:26
User entered 'No (N)'	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A84A275-93DF-48E7-9048-271F6E9DB738)', Time: '2020-08-13T14:07:23', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'fc6fc4a2-69dc-4d6a-ab35-68aafe465e76' User entered '13 Aug 2020 14:07'	System	13 Aug 2020 18:07:26
	System	13 Aug 2020 18:07:26

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:50:54

US3182236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:31:42
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 15:07:46

US3182236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:31:42
User entered '14 Aug 2020'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 15:07:46

US3182236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:31:42
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 15:07:46

US3182236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:31:42
User entered empty.	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 15:07:46

US3182236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:31:49
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:19:15

US3182236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	24 Aug 2020 13:19:15

US3182236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:07
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:19:24

US3182236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:07
User entered '21 Aug 2020'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:19:24

US3182236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:07
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:19:24

US3182236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:07
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:19:24

US3182236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:12
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:19:29

US3182236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	24 Aug 2020 13:19:29

US3182236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:24
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:10:14

US3182236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:24
User entered '28 Aug 2020'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:10:14

US3182236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:24
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:10:14

US3182236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:24
User entered empty.	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:10:14

US3182236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:32:31
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	31 Aug 2020 13:10:19

US3182236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	31 Aug 2020 13:10:19

US3182236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:47:03
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:08

US3182236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:47:03
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:08

US3182236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[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 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:47:03
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:08

US3182236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'VISIT2'	System	22 Sep 2020 17:51:08

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	22 Sep 2020 17:51:54
	(b) (4)	

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '12:19'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '10 Sep 2020 12:19'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '98.6' F	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered empty.	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '72'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'bpm'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '16'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'breaths/min'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '129'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '83'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '13:46'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '10 Sep 2020 13:46'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '97.6' F	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered empty.	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '64'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'bpm'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '16'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'breaths/min'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '152'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:54:53
User entered '95'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	22 Sep 2020 17:51:54

US3182236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:52:12

US3182236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:16
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:52:12

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:39
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:39
User entered empty.	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

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 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:39
User entered empty.	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:39
User entered '10 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:39
User entered '13:09'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '10 Sep 2020 13:09'	System	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:39
User entered 'Left Arm (LEFT ARM)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 15:55:39
User entered 'ONCE'	System	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 17:13:49

US3182236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:58
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	23 Sep 2020 17:22:06

US3182236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:58
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	23 Sep 2020 17:22:06

US3182236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:58
User entered '13:04'	Cassie Uminski (b) (4) (b) (4)	23 Sep 2020 17:22:06

US3182236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '10 Sep 2020 13:04'	System	23 Sep 2020 17:22:06

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:46
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	22 Sep 2020 17:52:23
	(b) (4)	

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:46
User entered '12:25'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:37:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '10 Sep 2020 12:25'	System	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:46
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:37:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered empty.	System	22 Sep 2020 17:52:23

US3182236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:57:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Sep 2020 17:56:53

US3182236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'I'	System	22 Sep 2020 17:56:53

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:42:48', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ec654dfd-9679-4939-9599-7b90c63a4e66' User entered 'Yes (Y)'	System	10 Sep 2020 17:43:17
	System	10 Sep 2020 17:43:17

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:42:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ec654dfd-9679-4939-9599-7b90c63a4e66' User entered '97.6'	System	10 Sep 2020 17:43:17
	System	10 Sep 2020 17:43:17

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:43:02', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ec654dfd-9679-4939-9599-7b90c63a4e66'	System	10 Sep 2020 17:43:17
User entered 'No (N)'	System	10 Sep 2020 17:43:17

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:43:13', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ec654dfd-9679-4939-9599-7b90c63a4e66' User entered '10 Sep 2020 13:43'	System	10 Sep 2020 17:43:17
	System	10 Sep 2020 17:43:17

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 15:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:10:42', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6a530fb7-d4d6-41fa-9d26-19565a884d64' User entered 'Yes (Y)'	System	11 Sep 2020 01:13:03
	System	11 Sep 2020 01:13:03

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:12:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6a530fb7-d4d6-41fa-9d26-19565a884d64' User entered '97.9'	System	11 Sep 2020 01:13:03
	System	11 Sep 2020 01:13:03

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:12:53', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6a530fb7-d4d6-41fa-9d26-19565a884d64' User entered 'No (N)'	System	11 Sep 2020 01:13:03
	System	11 Sep 2020 01:13:03

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:12:58', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6a530fb7-d4d6-41fa-9d26-19565a884d64' User entered '10 Sep 2020 21:12'	System	11 Sep 2020 01:13:03
	System	11 Sep 2020 01:13:03

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 16:54'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 2'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:36:11', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '55f221fc-2bf0-49ab-912b-53902ecbdbcc' User entered 'Yes (Y)'	System	12 Sep 2020 10:39:43
	System	12 Sep 2020 10:39:43

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:39:30', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '55f221fc-2bf0-49ab-912b-53902ecbdbcc' User entered '96.2'	System	12 Sep 2020 10:39:43
	System	12 Sep 2020 10:39:43

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:39:35', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '55f221fc-2bf0-49ab-912b-53902ecbdbcc'	System	12 Sep 2020 10:39:43
User entered 'No (N)'	System	12 Sep 2020 10:39:43

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:39:37', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '55f221fc-2bf0-49ab-912b-53902ecbdbcc' User entered '12 Sep 2020 06:39'	System	12 Sep 2020 10:39:43
	System	12 Sep 2020 10:39:43

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 3'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:24:45', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '87e64e20-2266-45be-951a-ae8948a1bc0b' User entered 'Yes (Y)'	System	13 Sep 2020 00:25:34
	System	13 Sep 2020 00:25:34

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:25:22', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '87e64e20-2266-45be-951a-ae8948a1bc0b' User entered '94.5'	System	13 Sep 2020 00:25:34
	System	13 Sep 2020 00:25:34

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:25:25', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '87e64e20-2266-45be-951a-ae8948a1bc0b' User entered 'No (N)'	System	13 Sep 2020 00:25:34
	System	13 Sep 2020 00:25:34

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:25:30', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '87e64e20-2266-45be-951a-ae8948a1bc0b' User entered '12 Sep 2020 20:25'	System	13 Sep 2020 00:25:34
	System	13 Sep 2020 00:25:34

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 4'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:06:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'd1e064ec-75a6-409e-89c1-32569fb4b8bd' User entered 'Yes (Y)'	System	14 Sep 2020 00:08:20
	System	14 Sep 2020 00:08:20

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:07:55', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'd1e064ec-75a6-409e-89c1-32569fb4b8bd' User entered '98.1'	System	14 Sep 2020 00:08:20
	System	14 Sep 2020 00:08:20

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:07:59', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'd1e064ec-75a6-409e-89c1-32569fb4b8bd' User entered 'No (N)'	System	14 Sep 2020 00:08:20
	System	14 Sep 2020 00:08:20

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:08:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'd1e064ec-75a6-409e-89c1-32569fb4b8bd' User entered '13 Sep 2020 20:08'	System	14 Sep 2020 00:08:20
	System	14 Sep 2020 00:08:20

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 5'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ce492dc2-07c8-4749-960a-7a8bcbcd476c' User entered 'Yes (Y)'	System	14 Sep 2020 22:19:18
	System	14 Sep 2020 22:19:18

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:19:06', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ce492dc2-07c8-4749-960a-7a8bcbcd476c' User entered '96.6'	System	14 Sep 2020 22:19:18
	System	14 Sep 2020 22:19:18

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:19:11', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ce492dc2-07c8-4749-960a-7a8bcbcd476c' User entered 'No (N)'	System	14 Sep 2020 22:19:18
	System	14 Sep 2020 22:19:18

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:19:14', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ce492dc2-07c8-4749-960a-7a8bcbcd476c' User entered '14 Sep 2020 18:19'	System	14 Sep 2020 22:19:18
	System	14 Sep 2020 22:19:18

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 6'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:01:04', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'c0dae771-692b-4b2e-8321-4a1e8b97b5bd' User entered 'Yes (Y)'	System	16 Sep 2020 01:02:07
	System	16 Sep 2020 01:02:07

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:01:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'c0dae771-692b-4b2e-8321-4a1e8b97b5bd' User entered '97.0'	System	16 Sep 2020 01:02:07
	System	16 Sep 2020 01:02:07

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:02:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'c0dae771-692b-4b2e-8321-4a1e8b97b5bd' User entered 'No (N)'	System	16 Sep 2020 01:02:07
	System	16 Sep 2020 01:02:07

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:02:03', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'c0dae771-692b-4b2e-8321-4a1e8b97b5bd' User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:02:07
	System	16 Sep 2020 01:02:07

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 7'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:44:09', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f39cd009-f992-4705-8995-3914ca8005ca' User entered 'Yes (Y)'	System	17 Sep 2020 00:45:23
	System	17 Sep 2020 00:45:23

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:45:12', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f39cd009-f992-4705-8995-3914ca8005ca' User entered '97.5'	System	17 Sep 2020 00:45:23
	System	17 Sep 2020 00:45:23

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:45:17', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f39cd009-f992-4705-8995-3914ca8005ca' User entered 'No (N)'	System	17 Sep 2020 00:45:23
	System	17 Sep 2020 00:45:23

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:45:21', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'f39cd009-f992-4705-8995-3914ca8005ca' User entered '16 Sep 2020 20:45'	System	17 Sep 2020 00:45:23
	System	17 Sep 2020 00:45:23

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:43:50', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0bd3bec9-5e92-4360-abd0-b0ef70be1c1c' User entered 'None (1)'	System	10 Sep 2020 17:44:06
	System	10 Sep 2020 17:44:06

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:43:53', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0bd3bec9-5e92-4360-abd0-b0ef70be1c1c' User entered 'No (N)'	System	10 Sep 2020 17:44:06
	System	10 Sep 2020 17:44:06

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:43:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0bd3bec9-5e92-4360-abd0-b0ef70be1c1c' User entered 'No (N)'	System	10 Sep 2020 17:44:06
	System	10 Sep 2020 17:44:06

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0bd3bec9-5e92-4360-abd0-b0ef70be1c1c' User entered 'None (1)'	System	10 Sep 2020 17:44:06
	System	10 Sep 2020 17:44:06

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:04', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0bd3bec9-5e92-4360-abd0-b0ef70be1c1c' User entered '10 Sep 2020 13:44'	System	10 Sep 2020 17:44:06
	System	10 Sep 2020 17:44:06

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 15:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:16', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07961f3a-25f5-40c5-a5a0-065a4d7d9c25'	System	11 Sep 2020 01:13:38
User entered 'None (1)'	System	11 Sep 2020 01:13:38

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:20', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07961f3a-25f5-40c5-a5a0-065a4d7d9c25' User entered 'No (N)'	System	11 Sep 2020 01:13:38
	System	11 Sep 2020 01:13:38

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:25', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07961f3a-25f5-40c5-a5a0-065a4d7d9c25' User entered 'No (N)'	System	11 Sep 2020 01:13:38
	System	11 Sep 2020 01:13:38

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:31', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07961f3a-25f5-40c5-a5a0-065a4d7d9c25'	System	11 Sep 2020 01:13:38
User entered 'None (1)'	System	11 Sep 2020 01:13:38

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:36', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '07961f3a-25f5-40c5-a5a0-065a4d7d9c25' User entered '10 Sep 2020 21:13'	System	11 Sep 2020 01:13:38
	System	11 Sep 2020 01:13:38

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 16:54'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 2'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e7f54b7-75bd-4feb-a708-becdf93cbd7d' User entered 'None (1)'	System	12 Sep 2020 10:33:32
	System	12 Sep 2020 10:33:32

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:12', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e7f54b7-75bd-4feb-a708-becdf93cbd7d' User entered 'No (N)'	System	12 Sep 2020 10:33:32
	System	12 Sep 2020 10:33:32

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:18', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e7f54b7-75bd-4feb-a708-becdf93cbd7d' User entered 'No (N)'	System	12 Sep 2020 10:33:32
	System	12 Sep 2020 10:33:32

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:23', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e7f54b7-75bd-4feb-a708-becdf93cbd7d' User entered 'None (1)'	System	12 Sep 2020 10:33:32
	System	12 Sep 2020 10:33:32

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:27', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e7f54b7-75bd-4feb-a708-becdf93cbd7d' User entered '12 Sep 2020 06:33'	System	12 Sep 2020 10:33:32
	System	12 Sep 2020 10:33:32

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 3'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:24:19', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '233a272f-ffab-4ed5-a51f-f201797ea24a' User entered 'None (1)'	System	13 Sep 2020 00:25:01
	System	13 Sep 2020 00:25:01

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:24:23', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '233a272f-ffab-4ed5-a51f-f201797ea24a' User entered 'No (N)'	System	13 Sep 2020 00:25:01
	System	13 Sep 2020 00:25:01

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:24:26', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '233a272f-ffab-4ed5-a51f-f201797ea24a' User entered 'No (N)'	System	13 Sep 2020 00:25:01
	System	13 Sep 2020 00:25:01

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:24:29', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '233a272f-ffab-4ed5-a51f-f201797ea24a' User entered 'None (1)'	System	13 Sep 2020 00:25:01
	System	13 Sep 2020 00:25:01

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:24:35', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '233a272f-ffab-4ed5-a51f-f201797ea24a' User entered '12 Sep 2020 20:24'	System	13 Sep 2020 00:25:01
	System	13 Sep 2020 00:25:01

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 4'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:41', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6eb2f4c6-9e95-4d40-b65c-6384950e56d2' User entered 'None (1)'	System	14 Sep 2020 00:07:51
	System	14 Sep 2020 00:07:51

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6eb2f4c6-9e95-4d40-b65c-6384950e56d2' User entered 'No (N)'	System	14 Sep 2020 00:07:51
	System	14 Sep 2020 00:07:51

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:46', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6eb2f4c6-9e95-4d40-b65c-6384950e56d2' User entered 'No (N)'	System	14 Sep 2020 00:07:51
	System	14 Sep 2020 00:07:51

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6eb2f4c6-9e95-4d40-b65c-6384950e56d2' User entered 'None (1)'	System	14 Sep 2020 00:07:51
	System	14 Sep 2020 00:07:51

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:53', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '6eb2f4c6-9e95-4d40-b65c-6384950e56d2' User entered '13 Sep 2020 20:05'	System	14 Sep 2020 00:07:51
	System	14 Sep 2020 00:07:51

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 5'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:26', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'be5cf5c6-b8c7-4c2e-a6d7-b89c61f55689' User entered 'None (1)'	System	14 Sep 2020 22:18:39
	System	14 Sep 2020 22:18:39

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:29', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'be5cf5c6-b8c7-4c2e-a6d7-b89c61f55689' User entered 'No (N)'	System	14 Sep 2020 22:18:39
	System	14 Sep 2020 22:18:39

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:32', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'be5cf5c6-b8c7-4c2e-a6d7-b89c61f55689' User entered 'No (N)'	System	14 Sep 2020 22:18:39
	System	14 Sep 2020 22:18:39

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:35', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'be5cf5c6-b8c7-4c2e-a6d7-b89c61f55689' User entered 'None (1)'	System	14 Sep 2020 22:18:39
	System	14 Sep 2020 22:18:39

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:38', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'be5cf5c6-b8c7-4c2e-a6d7-b89c61f55689' User entered '14 Sep 2020 18:18'	System	14 Sep 2020 22:18:39
	System	14 Sep 2020 22:18:39

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 6'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '906c09f6-b299-4f8e-b9f0-5627a4af7d90'	System	16 Sep 2020 01:00:59
User entered 'None (1)'	System	16 Sep 2020 01:00:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '906c09f6-b299-4f8e-b9f0-5627a4af7d90' User entered 'No (N)'	System	16 Sep 2020 01:00:59
	System	16 Sep 2020 01:00:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '906c09f6-b299-4f8e-b9f0-5627a4af7d90' User entered 'No (N)'	System	16 Sep 2020 01:00:59
	System	16 Sep 2020 01:00:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:52', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '906c09f6-b299-4f8e-b9f0-5627a4af7d90' User entered 'None (1)'	System	16 Sep 2020 01:00:59
	System	16 Sep 2020 01:00:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:55', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '906c09f6-b299-4f8e-b9f0-5627a4af7d90' User entered '15 Sep 2020 21:00'	System	16 Sep 2020 01:00:59
	System	16 Sep 2020 01:00:59

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 7'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '5078f710-0912-4ad7-84a3-217557443908' User entered 'None (1)'	System	17 Sep 2020 00:44:04
	System	17 Sep 2020 00:44:04

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:51', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '5078f710-0912-4ad7-84a3-217557443908' User entered 'No (N)'	System	17 Sep 2020 00:44:04
	System	17 Sep 2020 00:44:04

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '5078f710-0912-4ad7-84a3-217557443908' User entered 'No (N)'	System	17 Sep 2020 00:44:04
	System	17 Sep 2020 00:44:04

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:57', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '5078f710-0912-4ad7-84a3-217557443908'	System	17 Sep 2020 00:44:04
User entered 'None (1)'	System	17 Sep 2020 00:44:04

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:44:02', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '5078f710-0912-4ad7-84a3-217557443908'	System	17 Sep 2020 00:44:04
User entered '16 Sep 2020 20:44'	System	17 Sep 2020 00:44:04

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:09', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99' User entered 'None (0)'	System	10 Sep 2020 17:44:30
	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:11', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99' User entered 'None (0)'	System	10 Sep 2020 17:44:30
	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:14', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99' User entered 'None (0)'	System	10 Sep 2020 17:44:30
	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:17', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99' User entered 'None (0)'	System	10 Sep 2020 17:44:30
	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:20', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99' User entered 'None (0)'	System	10 Sep 2020 17:44:30
	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:22', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99' User entered 'None (0)'	System	10 Sep 2020 17:44:30
	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:25', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99' User entered 'No (N)'	System	10 Sep 2020 17:44:30
	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T13:44:28', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8462f780-23c2-460d-8a99-ef746b201b99'	System	10 Sep 2020 17:44:30
User entered '10 Sep 2020 13:44'	System	10 Sep 2020 17:44:30

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 15:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:41', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered 'None (0)'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered 'None (0)'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered 'None (0)'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered 'None (0)'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:52', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered 'None (0)'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered 'None (0)'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:13:57', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered 'No (N)'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-10T21:14:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9996be90-5a66-4792-857a-8fe7bebe258f' User entered '10 Sep 2020 21:14'	System	11 Sep 2020 01:14:01
	System	11 Sep 2020 01:14:01

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '10 Sep 2020 16:54'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 2'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:34', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248' User entered 'None (0)'	System	12 Sep 2020 10:33:59
	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:37', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248' User entered 'None (0)'	System	12 Sep 2020 10:33:59
	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:40', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248' User entered 'None (0)'	System	12 Sep 2020 10:33:59
	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248' User entered 'None (0)'	System	12 Sep 2020 10:33:59
	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248' User entered 'None (0)'	System	12 Sep 2020 10:33:59
	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248' User entered 'None (0)'	System	12 Sep 2020 10:33:59
	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:53', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248'	System	12 Sep 2020 10:33:59
User entered 'No (N)'	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T06:33:55', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'dcdfc083-e761-46d3-a76c-12f5644af248' User entered '12 Sep 2020 06:33'	System	12 Sep 2020 10:33:59
	System	12 Sep 2020 10:33:59

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 3'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:42', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered 'None (0)'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered 'None (0)'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered 'None (0)'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:50', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered 'None (0)'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:52', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered 'None (0)'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:53', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered 'None (0)'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered 'No (N)'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-12T20:23:59', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '0fa3f396-e9b9-45e5-bfd8-1d42dfea6b2f' User entered '12 Sep 2020 20:23'	System	13 Sep 2020 00:24:35
	System	13 Sep 2020 00:24:35

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 4'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:20', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered 'None (0)'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:24', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered 'None (0)'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:26', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered 'None (0)'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:28', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered 'None (0)'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:30', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered 'None (0)'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:32', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered 'None (0)'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:35', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered 'No (N)'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-13T20:05:37', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'edb1e222-3b0f-4a8a-b5e2-4152b5a4fab8' User entered '13 Sep 2020 20:05'	System	14 Sep 2020 00:07:42
	System	14 Sep 2020 00:07:42

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 5'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:02', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered 'None (0)'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:06', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered 'None (0)'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered 'None (0)'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:10', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered 'None (0)'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:13', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered 'None (0)'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:15', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered 'None (0)'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:19', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered 'No (N)'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-14T18:18:22', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '797429c3-4ecc-486e-ae37-33301f4961d1' User entered '14 Sep 2020 18:18'	System	14 Sep 2020 22:18:25
	System	14 Sep 2020 22:18:25

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 6'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:07', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered 'None (0)'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:10', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered 'None (0)'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:12', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered 'None (0)'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:14', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered 'None (0)'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:16', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered 'None (0)'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:18', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered 'None (0)'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:20', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered 'No (N)'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-15T21:00:24', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '614ab028-641b-4f98-88cd-8c16f8a1bab5' User entered '15 Sep 2020 21:00'	System	16 Sep 2020 01:00:26
	System	16 Sep 2020 01:00:26

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	10 Sep 2020 17:13:49
User entered 'Day 7'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:13', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered 'None (0)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:15', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered 'None (0)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:23', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered 'None (0)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:28', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered 'None (0)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:34', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered 'None (0)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:36', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered 'None (0)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:38', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered 'No (N)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-09-16T20:43:43', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9632edd7-8ee6-4c65-b6be-14630e4045f9' User entered '16 Sep 2020 20:43'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:13:49

US3182236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:37:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:13:49

US3182236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:36
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:05:01

US3182236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:36
User entered '17 Sep 2020'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:05:01

US3182236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:36
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:05:01

US3182236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:36
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:05:01

US3182236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:24:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:40
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:05:05

US3182236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	24 Sep 2020 15:05:05

US3182236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:53
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:44:40

US3182236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:53
User entered '24 Sep 2020'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:44:40

US3182236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:53
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:44:40

US3182236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:59:53
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:44:40

US3182236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:00
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:44:33

US3182236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	24 Sep 2020 18:44:33

US3182236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:09
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	01 Oct 2020 16:54:30

US3182236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:09
User entered '1 Oct 2020'	Alec Ireland (b) (4) (b) (4)	01 Oct 2020 16:54:30

US3182236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:09
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	01 Oct 2020 16:54:30

US3182236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:09
User entered empty.	Alec Ireland (b) (4) (b) (4)	01 Oct 2020 16:54:30

US3182236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:18
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	01 Oct 2020 16:54:22

US3182236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	01 Oct 2020 16:54:22

US3182236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:17:50

US3182236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:45
User entered '08 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:17:50

US3182236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[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 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:45
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:17:50

US3182236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'VISIT3'	System	14 Oct 2020 15:17:50

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered '08 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered '13:57'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '08 Oct 2020 13:57'	System	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered '97.5' F	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered '60'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'bpm'	System	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered '14'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'breaths/min'	System	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered '146'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:12
User entered '88'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'mmHg'	System	14 Oct 2020 15:18:08

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59

US3182236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59

US3182236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:28
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:23

US3182236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:28
User entered empty.	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:23

US3182236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:33

US3182236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:40
User entered '08 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:33

US3182236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:40
User entered '14:06'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:33

US3182236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered '08 Oct 2020 14:06'	System	14 Oct 2020 15:18:33

US3182236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:19:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:03:47
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:18:40

US3182236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:59
User entered 'I'	System	14 Oct 2020 15:18:40

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 64'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-10-08T14:24:26', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '2a0dfb08-b8a8-46bd-b87a-c9fdd356bf7c' User entered 'No (N)'	System	08 Oct 2020 18:24:41
	System	08 Oct 2020 18:24:41

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with 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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-10-08T14:24:33', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '2a0dfb08-b8a8-46bd-b87a-c9fdd356bf7c' User entered 'No (N)'	System	08 Oct 2020 18:24:41
	System	08 Oct 2020 18:24:41

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-10-08T14:24:40', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '2a0dfb08-b8a8-46bd-b87a-c9fdd356bf7c' User entered '08 Oct 2020 14:24:40'	System	08 Oct 2020 18:24:41
	System	08 Oct 2020 18:24:41

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 71'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 78'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3182236

Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 92'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 99'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-11-12T15:48:52', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b99d7569-18da-4916-8fc4-dfd77e90d33e' User entered 'No (N)'	System	12 Nov 2020 20:49:36
	System	12 Nov 2020 20:49:36

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with 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 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-11-12T15:49:11', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b99d7569-18da-4916-8fc4-dfd77e90d33e' User entered 'No (N)'	System	12 Nov 2020 20:49:36
	System	12 Nov 2020 20:49:36

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-11-12T15:49:31', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b99d7569-18da-4916-8fc4-dfd77e90d33e' User entered '12 Nov 2020 15:49:31'	System	12 Nov 2020 20:49:36
	System	12 Nov 2020 20:49:36

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:16:01
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered 'Day 106'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 19:50:54

US3182236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:11:49
Data entry locked.	System	07 Aug 2020 19:50:54
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 19:50:54

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-03T13:56:54', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8c2d25d5-eb94-4fa0-8be0-246759de8e27'	System	03 Dec 2020 18:57:12
User entered 'No (N)'	System	03 Dec 2020 18:57:12

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-03T13:57:02', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8c2d25d5-eb94-4fa0-8be0-246759de8e27'	System	03 Dec 2020 18:57:12
User entered 'No (N)'	System	03 Dec 2020 18:57:12

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-03T13:57:09', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '8c2d25d5-eb94-4fa0-8be0-246759de8e27' User entered '03 Dec 2020 13:57:09'	System	03 Dec 2020 18:57:12
	System	03 Dec 2020 18:57:12

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-09T20:53:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9006cd93-af21-4a3e-a91e-506b02439f42'	System	10 Dec 2020 01:54:22
User entered 'No (N)'	System	10 Dec 2020 01:54:22

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-09T20:54:06', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9006cd93-af21-4a3e-a91e-506b02439f42'	System	10 Dec 2020 01:54:22
User entered 'No (N)'	System	10 Dec 2020 01:54:22

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-09T20:54:14', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '9006cd93-af21-4a3e-a91e-506b02439f42' User entered '09 Dec 2020 20:54:14'	System	10 Dec 2020 01:54:22
	System	10 Dec 2020 01:54:22

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-17T15:33:21', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'a9b19ff4-e391-4491-9dbc-b5490f554042'	System	17 Dec 2020 20:33:33
User entered 'No (N)'	System	17 Dec 2020 20:33:33

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-17T15:33:25', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'a9b19ff4-e391-4491-9dbc-b5490f554042'	System	17 Dec 2020 20:33:33
User entered 'No (N)'	System	17 Dec 2020 20:33:33

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-17T15:33:29', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'a9b19ff4-e391-4491-9dbc-b5490f554042' User entered '17 Dec 2020 15:33:29'	System	17 Dec 2020 20:33:33
	System	17 Dec 2020 20:33:33

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-27T11:47:49', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ee953813-47c0-4424-bd9e-d6b69e9d7e86'	System	27 Dec 2020 16:48:17
User entered 'No (N)'	System	27 Dec 2020 16:48:17

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-27T11:48:06', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ee953813-47c0-4424-bd9e-d6b69e9d7e86'	System	27 Dec 2020 16:48:17
User entered 'No (N)'	System	27 Dec 2020 16:48:17

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2020-12-27T11:48:14', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ee953813-47c0-4424-bd9e-d6b69e9d7e86' User entered '27 Dec 2020 11:48:14'	System	27 Dec 2020 16:48:17
	System	27 Dec 2020 16:48:17

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-05T17:31:47', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bd9aa7d7-2ecd-42a9-9b49-3c244405809e' User entered 'No (N)'	System	05 Jan 2021 22:32:07
	System	05 Jan 2021 22:32:07

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-05T17:31:55', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bd9aa7d7-2ecd-42a9-9b49-3c244405809e' User entered 'No (N)'	System	05 Jan 2021 22:32:07

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-05T17:32:01', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'bd9aa7d7-2ecd-42a9-9b49-3c244405809e' User entered '05 Jan 2021 17:32:01'	System	05 Jan 2021 22:32:07
	System	05 Jan 2021 22:32:07

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-20T18:00:59', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b063066a-39d1-4027-9320-a63ad29ab214'	System	20 Jan 2021 23:01:46
User entered 'Yes (Y)'	System	20 Jan 2021 23:01:46

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-20T18:01:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b063066a-39d1-4027-9320-a63ad29ab214'	System	20 Jan 2021 23:01:46
User entered 'No (N)'	System	20 Jan 2021 23:01:46

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-20T18:01:14', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b063066a-39d1-4027-9320-a63ad29ab214'	System	20 Jan 2021 23:01:46
User entered 'No (N)'	System	20 Jan 2021 23:01:46

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-20T18:01:24', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b063066a-39d1-4027-9320-a63ad29ab214' User entered 'No (N)'	System	20 Jan 2021 23:01:46

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-20T18:01:34', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'b063066a-39d1-4027-9320-a63ad29ab214' User entered '20 Jan 2021 18:01:34'	System	20 Jan 2021 23:01:46
	System	20 Jan 2021 23:01:46

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-28T11:59:42', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e88a2ab-3c26-4313-a0d3-5504bb3b2c5d' User entered 'Yes (Y)'	System	28 Jan 2021 17:05:57
	System	28 Jan 2021 17:05:57

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-28T12:00:05', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e88a2ab-3c26-4313-a0d3-5504bb3b2c5d'	System	28 Jan 2021 17:05:57
User entered 'No (N)'	System	28 Jan 2021 17:05:57

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-28T12:00:11', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e88a2ab-3c26-4313-a0d3-5504bb3b2c5d'	System	28 Jan 2021 17:05:57
User entered 'No (N)'	System	28 Jan 2021 17:05:57

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-28T12:00:28', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e88a2ab-3c26-4313-a0d3-5504bb3b2c5d'	System	28 Jan 2021 17:05:57
User entered 'No (N)'	System	28 Jan 2021 17:05:57

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-01-28T12:00:58', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '3e88a2ab-3c26-4313-a0d3-5504bb3b2c5d' User entered '28 Jan 2021 12:00:58'	System	28 Jan 2021 17:05:57

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-03T18:31:32', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '908630c6-5b76-41d3-b0ba-2daffe1c5e17e' User entered 'Yes (Y)'	System	03 Feb 2021 23:32:10
	System	03 Feb 2021 23:32:10

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-03T18:31:38', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '908630c6-5b76-41d3-b0ba-2daffe1c5e17e' User entered 'No (N)'	System	03 Feb 2021 23:32:10
	System	03 Feb 2021 23:32:10

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-03T18:31:44', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '908630c6-5b76-41d3-b0ba-2daffe1c5e17e' User entered 'No (N)'	System	03 Feb 2021 23:32:10
	System	03 Feb 2021 23:32:10

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-03T18:31:56', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '908630c6-5b76-41d3-b0ba-2daffe1c5e17e' User entered 'No (N)'	System	03 Feb 2021 23:32:10
	System	03 Feb 2021 23:32:10

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-03T18:32:06', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '908630c6-5b76-41d3-b0ba-2daffe1c5e17e' User entered '03 Feb 2021 18:32:06'	System	03 Feb 2021 23:32:10
	System	03 Feb 2021 23:32:10

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-17T17:34:57', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '71d40467-823a-438c-b6ce-360a3ff6ff40' User entered 'Yes (Y)'	System	17 Feb 2021 22:35:26
	System	17 Feb 2021 22:35:26

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-17T17:35:02', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '71d40467-823a-438c-b6ce-360a3ff6ff40'	System	17 Feb 2021 22:35:26
User entered 'No (N)'	System	17 Feb 2021 22:35:26

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-17T17:35:08', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '71d40467-823a-438c-b6ce-360a3ff6ff40'	System	17 Feb 2021 22:35:26
User entered 'No (N)'	System	17 Feb 2021 22:35:26

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-17T17:35:18', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '71d40467-823a-438c-b6ce-360a3ff6ff40'	System	17 Feb 2021 22:35:26
User entered 'No (N)'	System	17 Feb 2021 22:35:26

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-17T17:35:21', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '71d40467-823a-438c-b6ce-360a3ff6ff40' User entered '17 Feb 2021 17:35:21'	System	17 Feb 2021 22:35:26
	System	17 Feb 2021 22:35:26

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-22T15:45:45', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '055d977f-d01d-4c12-b71f-cd8a31f027e2' User entered 'No (N)'	System	22 Feb 2021 20:45:58
	System	22 Feb 2021 20:45:58

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-22T15:45:50', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '055d977f-d01d-4c12-b71f-cd8a31f027e2'	System	22 Feb 2021 20:45:58
User entered 'No (N)'	System	22 Feb 2021 20:45:58

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-02-22T15:45:53', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '055d977f-d01d-4c12-b71f-cd8a31f027e2'	System	22 Feb 2021 20:45:58
User entered '22 Feb 2021 15:45:53'	System	22 Feb 2021 20:45:58

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-23T15:53:23-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '382fdb6a-9e00-4baf-a71a-bee8dd9d5a9e'	System	23 Mar 2021 19:54:18
User entered 'No (N)'	System	23 Mar 2021 19:54:18

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-23T15:54:08-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '382fdb6a-9e00-4baf-a71a-bee8dd9d5a9e'	System	23 Mar 2021 19:54:18
User entered 'No (N)'	System	23 Mar 2021 19:54:18

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-23T15:54:16-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '382fdb6a-9e00-4baf-a71a-bee8dd9d5a9e'	System	23 Mar 2021 19:54:18
User entered '23 Mar 2021 15:54:16'	System	23 Mar 2021 19:54:18

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-29T12:32:36-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ebf4c063-4ef5-401b-9504-80b77b130616'	System	29 Mar 2021 16:33:21
User entered 'Yes (Y)'	System	29 Mar 2021 16:33:21

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-29T12:32:41-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ebf4c063-4ef5-401b-9504-80b77b130616'	System	29 Mar 2021 16:33:21
User entered 'No (N)'	System	29 Mar 2021 16:33:21

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-29T12:32:46-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ebf4c063-4ef5-401b-9504-80b77b130616'	System	29 Mar 2021 16:33:21
User entered 'No (N)'	System	29 Mar 2021 16:33:21

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-29T12:32:53-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ebf4c063-4ef5-401b-9504-80b77b130616'	System	29 Mar 2021 16:33:21
User entered 'Yes (Y)'	System	29 Mar 2021 16:33:21

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-29T12:33:02-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ebf4c063-4ef5-401b-9504-80b77b130616'	System	29 Mar 2021 16:33:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Mar 2021 16:33:21

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-29T12:33:07-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'ebf4c063-4ef5-401b-9504-80b77b130616' User entered '29 Mar 2021 12:33:07'	System	29 Mar 2021 16:33:21
	System	29 Mar 2021 16:33:21

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-04-20T14:20:24-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '42fb9252-feec-4abb-9109-7f8c683f539a' User entered 'No (N)'	System	20 Apr 2021 18:20:38

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-04-20T14:20:29-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '42fb9252-feec-4abb-9109-7f8c683f539a' User entered 'No (N)'	System	20 Apr 2021 18:20:38

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-04-20T14:20:34-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: '42fb9252-feec-4abb-9109-7f8c683f539a' User entered '20 Apr 2021 14:20:34'	System	20 Apr 2021 18:20:38
	System	20 Apr 2021 18:20:38

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:11:49

US3182236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:37:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:11:49
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:11:49

US3182236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:37:20

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-19T14:33:16-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'd716291c-6690-4618-8ca3-6e21643e98ea' User entered 'No (N)'	System	19 Mar 2021 18:33:25
	System	19 Mar 2021 18:33:25

US3182236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:37:20

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:55:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E864A3A-E032-4846-A683-35400A0137ED)', Time: '2021-03-19T14:33:22-04:00', User OID: 'PatientReportedOutcome (US3182236)', ODM File OID: 'd716291c-6690-4618-8ca3-6e21643e98ea' User entered '19 Mar 2021 14:33:22'	System	19 Mar 2021 18:33:25
	System	19 Mar 2021 18:33:25

US3182236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:59:30
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Nov 2020 16:50:19

US3182236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:59:30
User entered '05 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	13 Nov 2020 16:50:19

US3182236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:59:30
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	13 Nov 2020 16:50:19

US3182236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:59:30
User entered empty.	Cassie Uminski (b) (4) (b) (4)	13 Nov 2020 16:50:19

US3182236

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:59:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Nov 2020 16:50:26

US3182236

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:12:27
User entered 'I'	System	13 Nov 2020 16:50:26

US3182236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:17:37
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:29:05

US3182236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:17:37
User entered '08 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:29:05

US3182236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:17:37
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:29:05

US3182236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:17:37
User entered empty.	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:29:05

US3182236

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:17:29
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:28:55

US3182236

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User entered 'I'	System	21 Dec 2020 18:28:55

US3182236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:51:02
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 17:30:00

US3182236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:51:02
User entered '05 Jan 2021'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 17:30:00

US3182236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:51:02
User entered 'Contact Made (CONTACT MADE)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 17:30:00

US3182236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:51:02
User entered empty.	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 17:30:00

US3182236

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 17:51:07
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 17:30:07

US3182236

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:19
User entered 'I'	System	05 Jan 2021 17:30:07

US3182236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:16:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Feb 2021 20:30:59

US3182236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:16:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '04 Feb 2021'	Cassie Uminski (b) (4)	10 Feb 2021 20:30:59

US3182236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:16:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	10 Feb 2021 20:30:59

US3182236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:16:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered empty.	Cassie Uminski (b) (4)	10 Feb 2021 20:30:59

US3182236

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:16:29
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Feb 2021 20:30:23

US3182236

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered 'I'	System	10 Feb 2021 20:30:23

US3182236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:17:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:02:22

US3182236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:17:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:02:22

US3182236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:17:52
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	27 Feb 2021 05:02:22

US3182236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered 'VISIT4'	System	27 Feb 2021 05:02:22

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '09:10'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered '23 Feb 2021 09:10'	System	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '97.8' F	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered empty.	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '83'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered 'bpm'	System	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '16'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered 'breaths/min'	System	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '138'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered 'mmHg'	System	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:05
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '79'	Cassie Uminski (b) (4)	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered 'mmHg'	System	29 Mar 2021 19:23:44

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36

US3182236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36

US3182236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:41:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:02:34

US3182236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:41:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:02:34

US3182236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:42
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:06:34

US3182236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:42
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '23 Feb 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:06:34

US3182236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:45:42
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '09:21'	Jennifer Gaston (b) (4)	29 Mar 2021 19:06:34

US3182236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered '23 Feb 2021 09:21'	System	29 Mar 2021 19:06:34

US3182236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:41:36
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:02:40

US3182236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:47:36
User entered 'I'	System	27 Feb 2021 05:02:40

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:04:44

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:04:44

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	27 Feb 2021 05:04:44

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'UNBLND_DECIDE'	System	27 Feb 2021 05:04:44

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:34:19
User entered '0'	Cassie Uminski (b) (4)	09 Apr 2021 19:48:49
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 16:25:37

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:12:40
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:34:19
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4)	09 Apr 2021 19:49:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	09 Apr 2021 19:48:49
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:58:22
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:25:37

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '1'	System	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:37:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'I'	System	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '163.0' cm	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '81.5' kg	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '30.67485'	System	27 Feb 2021 05:07:08
DataPoint set to visible.	System	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '163.0' cm	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '81.5' kg	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '30.67485'	System	27 Feb 2021 05:07:08
DataPoint set to visible.	System	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '09:10'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '23 Feb 2021 09:10'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '97.8' F	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered empty.	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '83'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'bpm'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '16'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'breaths/min'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '138'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'mmHg'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '79'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'mmHg'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '163.0' cm	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '81.5' kg	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:37:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '30.67485'	System	27 Feb 2021 05:07:08
DataPoint set to visible.	System	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '10:06'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '23 Feb 2021 10:06'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '98.1' F	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered empty.	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '87'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'bpm'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '16'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'breaths/min'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '110'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'mmHg'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:46:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '73'	Cassie Uminski (b) (4)	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'mmHg'	System	27 Feb 2021 05:07:08

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:14:44

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:14:44

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered empty.	Cassie Uminski (b) (4)	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

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)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered empty.	Cassie Uminski (b) (4)	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'mRNA-1273'	System	27 Feb 2021 05:15:03
DataPoint set to visible.	System	27 Feb 2021 05:05:38

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '09:36'	Cassie Uminski (b) (4)	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '23 Feb 2021 09:36'	System	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:13
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Left Arm (LEFT ARM)'	Cassie Uminski (b) (4)	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:45:13
User entered 'ONCE'	System	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'INTRAMUSCULAR'	System	27 Feb 2021 05:15:03

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:44:37
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:15

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:44:37
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:15

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:44:37
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '09:21'	Cassie Uminski (b) (4)	27 Feb 2021 05:05:15

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '23 Feb 2021 09:21'	System	27 Feb 2021 05:05:15

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:04:56

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:04:56

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered '09:15'	Cassie Uminski (b) (4)	27 Feb 2021 05:04:56

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:37:20

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered '23 Feb 2021 09:15'	System	27 Feb 2021 05:04:56

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:42:53
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:15:11

US3182236

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:19:15
User entered 'I'	System	27 Feb 2021 05:15:11

US3182236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:45:16
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:00
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:04:45
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	14 Mar 2021 02:53:12
	(b) (4)	

US3182236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:45:16
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:00
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:04:45
	(b) (4)	
User entered '02 Mar 2021'	Cassie Uminski (b) (4)	14 Mar 2021 02:53:12
	(b) (4)	

US3182236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:45:16
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:00
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:04:45
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	14 Mar 2021 02:53:12

US3182236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:45:16
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:00
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:04:45
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	14 Mar 2021 02:53:12
	(b) (4)	

US3182236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:45:16
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:05
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:04:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	14 Mar 2021 02:53:17

US3182236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:45:16
User entered 'I'	System	14 Mar 2021 02:53:17

US3182236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:45:16
User entered '1'	System	14 Mar 2021 02:53:17
DataPoint set to visible.	System	14 Mar 2021 02:53:17

US3182236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:41
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:07:01

US3182236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:41
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '24 Mar 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:07:01

US3182236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:42:41
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Clinic (Clinic)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:07:01

US3182236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'OLD29'	System	29 Mar 2021 19:07:01

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '24 Mar 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '14:51'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered '24 Mar 2021 14:51'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '98.6' F	(b) (4) Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Oral (Oral)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered empty.	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '71'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'bpm'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '16'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'breaths/min'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '130'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'mmHg'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '85'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'mmHg'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Mar 2021 19:08:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 19:08:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Mar 2021 19:08:05
User entered empty.	System	29 Mar 2021 19:08:05
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '24 Mar 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '15:26'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered '24 Mar 2021 15:26'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '98.7' F	(b) (4) Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Oral (Oral)'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered empty.	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '73'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'bpm'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '16'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'breaths/min'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '130'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:05
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'mmHg'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:32
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '84'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'mmHg'	System	29 Mar 2021 19:08:05

US3182236

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:41
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:20

US3182236

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:41
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '24 Mar 2021'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:20
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:53
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:53
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered empty.	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

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)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:53
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered empty.	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'mRNA-1273'	System	29 Mar 2021 19:08:43
DataPoint set to visible.	System	14 Mar 2021 02:53:17

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:53
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '24 Mar 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:53
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered '14:56'	(b) (4)	
	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:43
	(b) (4)	

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered '24 Mar 2021 14:56'	System	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:53
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Left Arm (LEFT ARM)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:53
User entered 'ONCE'	System	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:37:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'INTRAMUSCULAR'	System	29 Mar 2021 19:08:43

US3182236

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:59
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:08:51

US3182236

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:48:38
User entered 'I'	System	29 Mar 2021 19:08:51

US3182236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:28:59
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:17
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 15:19:43
	(b) (4)	

US3182236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:28:59
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:17
	(b) (4)	
User entered '31 Mar 2021'	Cassie Uminski (b) (4)	07 Apr 2021 15:19:43
	(b) (4)	

US3182236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:28:59
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:17
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	07 Apr 2021 15:19:43
	(b) (4)	

US3182236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:37:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:28:59
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:17
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Apr 2021 15:19:43
	(b) (4)	

US3182236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:28:23
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:17
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 15:19:50
	(b) (4)	

US3182236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:37:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:19:50

US3182236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:18
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Apr 2021 14:56:52
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:18
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '21 Apr 2021'	Cassie Uminski (b) (4)	22 Apr 2021 14:56:52
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:18
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	22 Apr 2021 14:56:52
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:37:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	22 Apr 2021 14:56:52

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '21 Apr 2021'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '10:00'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Apr 2021 10:00'	System	22 Apr 2021 14:57:13

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '97.7' F	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '73'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Apr 2021 14:57:13

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '16'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Apr 2021 14:57:13

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '135'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 14:57:13

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:29
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '86'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:13
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:37:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 14:57:13

US3182236

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:38
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:40
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:37:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:38
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '21 Apr 2021'	Cassie Uminski (b) (4)	22 Apr 2021 14:57:40
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:46
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Apr 2021 14:58:32
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:46
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '21 Apr 2021'	Cassie Uminski (b) (4)	22 Apr 2021 14:58:32
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:27:46
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:11:18
	(b) (4)	
User entered '10:20'	Cassie Uminski (b) (4)	22 Apr 2021 14:58:32
	(b) (4)	

US3182236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:37:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Apr 2021 10:20'	System	22 Apr 2021 14:58:32

US3182236

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:37:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:50
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:06:46
User signature succeeded.	Mary Beth Manning	30 Mar 2021 14:56:23
DataPoint Un-verified.	(b) (4)	29 Mar 2021 19:04:08
Signature has been broken.	Jennifer Gaston (b) (4)	29 Mar 2021 19:04:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	29 Mar 2021 19:04:08
DataPoint Verified.	Jennifer Gaston (b) (4)	24 Mar 2021 12:25:57
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'No (N)'	(b) (4)	12 Feb 2021 14:08:11

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:27:00
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:28:14
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered	System	30 Mar 2021 16:46:36
'USA-US075-2021-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	30 Mar 2021 16:46:36

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:27:02
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS (BILATERAL KNEES). If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 02:02:46
User closed query 'PV Query: Was the SAE considered a worsening of the subject's medical history of osteoarthritis knee? If Yes, then kindly update the event verbatim to "worsening left knee osteoarthritis".' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:27:50
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Apr 2021 19:45:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 19:45:04
Query 'PV Query: Was the SAE considered a worsening of the subject's medical history of osteoarthritis knee? If Yes, then kindly update the event verbatim to "worsening left knee osteoarthritis".' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4)	09 Apr 2021 19:44:41
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS (BILATERAL KNEES). If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4)	09 Apr 2021 19:44:26
Data point term sent to Coder	System	09 Apr 2021 19:44:09
Coding entries removed.	Cassie Uminski (b) (4)	09 Apr 2021 19:44:02
User entered 'Worsening of LEFT KNEE OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Apr 2021 19:44:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was the SAE considered a worsening of the subject's medical history of osteoarthritis knee? If Yes, then kindly update the event verbatim to "worsening left knee osteoarthritis".' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:47:02
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OSTEOARTHRITIS (BILATERAL KNEES). If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:34:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 19:07:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 19:07:40
Data point term sent to Coder	System	29 Mar 2021 19:06:42
User entered 'Left Knee Osteoarthritis'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:07:51
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:07:54
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:07:57
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:37:15
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '18 Jan 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:23:01
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:41:57
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 19:44:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 19:44:02
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Apr 2021 19:44:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 19:05:50
User entered empty.	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Event end date is reported as 18 Jan 2021. Subject was discharged from hospital on 19 Jan 2021. Please consider updating event end date to date of hospital discharge.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:48:09
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:23:11
User entered '18 Jan 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:23:12
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:40:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Gaston (b) (4) (b) (4)	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As no overnight hospitalization was confirmed with no additional serious criteria being met, please reassess case seriousness and consider downgrading event from serious to non-serious.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:04:08
	(b) (4), (b) (6)	19 Apr 2021 19:42:05
Query 'PV Query: As no overnight hospitalization was confirmed with no additional serious criteria being met, please reassess case seriousness and consider downgrading event from serious to non-serious.' answered with 'Updated discharge date' (Site from Safety).	Cassie Uminski (b) (4)	19 Apr 2021 19:10:38
	(b) (4)	
User opened query 'PV Query: As no overnight hospitalization was confirmed with no additional serious criteria being met, please reassess case seriousness and consider downgrading event from serious to non-serious.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 18:06:14
	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:09
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:11
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:13
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:27:27
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'Correct as is' (Site from Safety).	Cassie Uminski (b) (4)	09 Apr 2021 19:46:00
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:46:41
User entered 'I'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:16
Query 'PV Query: As no overnight hospitalization was confirmed with no additional serious criteria being met, please reassess case seriousness and consider downgrading event from serious to non-serious.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:06:08
User opened query 'PV Query: As no overnight hospitalization was confirmed with no additional serious criteria being met, please reassess case seriousness and consider downgrading event from serious to non-serious.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:05:55
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '18 Jan 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per investigator progress note on 19Apr2021 discharge date was 19Jan2021 but CRF has 18Jan2021. Please clarify. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:20
	(b) (4), (b) (6)	19 Apr 2021 19:42:18
Query 'Per investigator progress note on 19Apr2021 discharge date was 19Jan2021 but CRF has 18Jan2021. Please clarify. ' answered with 'Updated' (Site from CRA). Signature has been broken.	Cassie Uminski (b) (4)	19 Apr 2021 19:10:52
	(b) (4)	19 Apr 2021 19:10:11
User entered '19 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	19 Apr 2021 19:10:11
User opened query 'Per investigator progress note on 19Apr2021 discharge date was 19Jan2021 but CRF has 18Jan2021. Please clarify. ' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 18:57:41
	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
User entered '18 Jan 2021'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:24
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:26
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:28
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:30
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:32
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:38
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:40
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:42
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:45
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:47
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:49
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 02:02:51
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4)	09 Apr 2021 19:45:01
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:35:04
User entered 'I'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:58
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:43:00
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:43:08
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please keep query open until records are available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:06:32
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable once reports available. Please keep query open until reports are available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:06:22
User closed query 'PV Query: Was the admission to hospital for left knee replacement surgery a planned admission and procedure?' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:28:05
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:27:59
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:27:34
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Records requested' (Site from Safety).	Cassie Uminski (b) (4)	09 Apr 2021 19:46:46
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Records requested' (Site from Safety).	Cassie Uminski (b) (4)	09 Apr 2021 19:46:28
Query 'PV Query: Was the admission to hospital for left knee replacement surgery a planned admission and procedure?' answered with 'yes' (Site from Safety).	Cassie Uminski (b) (4)	09 Apr 2021 19:43:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was the admission to hospital for left knee replacement surgery a planned admission and procedure?' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:47:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:47:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:46:53
User entered 'Subject presented to site for follow up visit, subject confirmed having a left knee replacement surgery on 1/18/2021. Medical Records Release sent to subject to obtain medical records.'	Jennifer Gaston (b) (4)	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:05:50

US3182236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:37:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Mar 2021 19:05:50

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:37:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:46:53
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:14:05

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:45:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:45:55
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:41:39
User coded data point as ATC: VARIOUS, ATC: HOMEOPATHIC PREPARATION, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:32:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:32:46
Data point term sent to Coder	System	21 Sep 2020 19:23:00
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:22:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:35:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 20:35:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Aug 2020 15:51:08
Data point term sent to Coder	System	17 Aug 2020 15:15:21
User entered 'Cortisone'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:30:18
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:22:10
User entered 'OSTEOARTHRITIS-BACK/ BILATERAL FEET/ BILATERAL KNEES/ BILATERAL ELBOWS/ BILATERAL SHOULDERS' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	21 Sep 2020 19:22:10
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Osteoarthritis'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'I'	Cassie Uminski (b) (4)	17 Aug 2020 15:15:07
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	17 Aug 2020 15:15:07
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'injection'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'other (OTHER)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yearly'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Other (OTHER)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Intraarticular'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:58:11
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	17 Aug 2020 15:15:07
User entered 'un UNK 2016'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 15:15:07
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:15:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:17:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:17:12
Data point term sent to Coder	System	17 Aug 2020 15:16:24
User entered 'Levothyroxine'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Hypothyroidism'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '112'	Cassie Uminski (b) (4)	17 Aug 2020 15:15:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'ug (ug)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'other (OTHER)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '6 times per week'	Cassie Uminski (b) (4)	17 Aug 2020 15:15:59
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:58:11
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	17 Aug 2020 15:15:59
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 15:15:59
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:15:59

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:17:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:17:13
Data point term sent to Coder	System	17 Aug 2020 15:16:25
User entered 'Mucinex'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'I'	Cassie Uminski (b) (4)	17 Aug 2020 15:16:23
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:58:11
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	17 Aug 2020 15:16:23
User entered 'un UNK 1995'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:16:23

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:18:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:18:14
Data point term sent to Coder	System	17 Aug 2020 15:17:26
User entered 'Naproxen'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Osteoarthritis'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '500'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:58:11
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	17 Aug 2020 15:16:49
User entered 'un UNK 2016'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 15:16:49
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:16:49

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 13:24:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:24:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Aug 2020 15:51:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:18:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:18:15
Data point term sent to Coder User entered 'Iron'	System Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:29 17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	17 Aug 2020 15:17:20
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '60'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:58:11
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	17 Aug 2020 15:17:20
User entered 'un UNK 1997'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 15:17:20
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:17:20

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:19:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:19:17
Data point term sent to Coder	System	17 Aug 2020 15:18:30
User entered 'Biotin'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Health Maintenance'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '3'	Cassie Uminski (b) (4)	17 Aug 2020 15:17:43
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 15:17:43
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:58:11
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	17 Aug 2020 15:17:43
User entered 'un UNK 2014'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 15:17:43

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 22:38:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:38:16
Data point term sent to Coder	System	14 Oct 2020 15:15:39
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:15:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:39:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:39:22
Data point term sent to Coder	System	07 Oct 2020 18:01:11
Coding entries removed.	Amy Maroun (b) (4) (b) (4)	07 Oct 2020 18:00:45
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:33:24

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Aug 2020 12:33:24
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	17 Aug 2020 15:18:30
User entered 'Omeprazole'	Cassie Uminski (b) (4)	17 Aug 2020 15:18:07
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:12
User closed query 'Per DM CLR: Please review if indication recorded is a medical condition and not the drug action. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:15:18
Query 'Per DM CLR: Please review if indication recorded is a medical condition and not the drug action. Reconcile and update as appropriate. ' answered with 'Data is correct as entered' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:15:18
User entered 'HEALTH MAINTENANCE for stomach protection' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	14 Oct 2020 15:15:07
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	07 Oct 2020 18:00:45
User entered 'health maintenance' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	07 Oct 2020 18:00:45
User opened query 'Per DM CLR: Please review if indication recorded is a medical condition and not the drug action. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 08:51:31
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Stomach Protection'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '40'	Cassie Uminski (b) (4)	17 Aug 2020 15:18:07
	(b) (4)	

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:58:11
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	17 Aug 2020 15:18:07
User entered 'un UNK 2016'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered '0'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:51:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:37:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 15:18:07

US3182236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:37:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:59:20
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:48:36
Signature has been broken.	Cassie Uminski (b) (4)	09 Mar 2021 16:19:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Mar 2021 16:19:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:41:39
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Feb 2021 14:08:25

US3182236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:39:51
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:48:36
	(b) (4)	
User entered '18 Jan 2021'	Cassie Uminski (b) (4)	09 Mar 2021 16:21:33
	(b) (4)	

US3182236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User closed query 'Please see protocol section 8.3.3 and report as an SAE and request medical records. Required since they were hospitalized overnight. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:36:09
Query 'Please see protocol section 8.3.3 and report as an SAE and request medical records. Required since they were hospitalized overnight. ' answered with 'Records requested and osteoarthritis was added as SAE' (Site from CRA).	Cassie Uminski (b) (4)	09 Apr 2021 19:40:26
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:40:01
User opened query 'Please see protocol section 8.3.3 and report as an SAE and request medical records. Required since they were hospitalized overnight. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 14:37:27
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:48:36
User entered 'Total Left knee replacement'	Cassie Uminski (b) (4)	09 Mar 2021 16:21:33

US3182236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:20

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:36:13
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:25:36
	(b) (4)	
DataPoint Un-verified.	Cassie Uminski (b) (4)	09 Apr 2021 19:45:32
	(b) (4)	
Signature has been broken.	Cassie Uminski (b) (4)	09 Apr 2021 19:45:32
	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Apr 2021 19:45:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:39:54
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:48:36
	(b) (4)	
User entered 'Medical History (MH)'	Cassie Uminski (b) (4)	09 Mar 2021 16:21:33
	(b) (4)	

US3182236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:37:20

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:39:56
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:48:36
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 16:21:33
	(b) (4)	

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:50
User entered	System	30 Mar 2021 16:46:36
'USA-US075-2021-MRNA-1273-P301000012'		

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Toby'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Jennifer'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Briskin'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Gaston'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '3619 Park East Drive, Suite 300'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered 'Beachwood'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'OH'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '44122'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
User entered 'US'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 15:07:19
User entered '2'	System	12 Apr 2021 17:28:49
User entered '1'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:50
User entered	System	30 Mar 2021 16:46:36
'USA-US075-2021-MRNA-1273-P301000012'		

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Toby'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Jennifer'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Briskin'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Gaston'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '3619 Park East Drive, Suite 300'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered 'Beachwood'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'OH'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '44122'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
User entered 'US'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 15:07:19
User entered '2'	System	12 Apr 2021 17:28:49
User entered '1'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
User entered '30/Mar/2021 12:48'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:37:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:50
User entered	System	30 Mar 2021 16:46:36
'USA-US075-2021-MRNA-1273-P301000012'		

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Toby'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Jennifer'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Briskin'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Gaston'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '3619 Park East Drive, Suite 300'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered 'Beachwood'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'OH'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '44122'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
User entered 'US'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 15:07:19
User entered '2'	System	12 Apr 2021 17:28:49
User entered '1'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '12/Apr/2021 13:28'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:37:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:50
User entered	System	30 Mar 2021 16:46:36
'USA-US075-2021-MRNA-1273-P301000012'		

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Yes (Y)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'No (N)'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Toby'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Jennifer'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
Un-reviewed for Safety.	System	12 Apr 2021 17:28:49
Signature has been broken.	System	12 Apr 2021 17:28:49
User entered 'Briskin'	System	12 Apr 2021 17:28:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'Gaston'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '3619 Park East Drive, Suite 300'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered 'Beachwood'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 16:47:54
User entered 'OH'	System	30 Mar 2021 16:46:36

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:25:51
User entered '44122'	System	12 Apr 2021 17:28:49

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:46:29
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:07:12
	(b) (4)	
User entered 'US'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:37:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 15:07:19
User entered '2'	System	12 Apr 2021 17:28:49
User entered '1'	System	30 Mar 2021 16:48:06

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 12:38:41
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:09
	(b) (4)	
User entered '20/Apr/2021 08:07'	System	20 Apr 2021 15:07:19

US3182236

Folder: SAE USA-US075-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:37:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 12:38:41
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:09
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 15:07:19