

US3182158 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:33:21

All time stamps listed in this document are displayed in GMT

US3182158

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

[Participant ID](#)

US3182158

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

US3182158

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:40:19

Generated On: 09 Jun 2021 15:33:21

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:40:19

Generated On: 09 Jun 2021 15:33:21

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:40:19

Generated On: 09 Jun 2021 15:33:21

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:40:19

Generated On: 09 Jun 2021 15:33:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:40:19

Generated On: 09 Jun 2021 15:33:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3182158

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	RIGHT VENTRICLE DYSPLASIA
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182158

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	CARDIAC STENTS
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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	BENIGN THYNOMA
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	BIPOLAR 2
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 00:08:25

Generated On: 09 Jun 2021 15:33:21

Condition	PINCHED NERVE IN NECK
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3182158

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:40:19

Generated On: 09 Jun 2021 15:33:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:37
Height (xxx.x)	173.3 cm
Weight (xxx.x)	90.0 kg
BMI (xxx.x)	29.96715 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:40:19

Generated On: 09 Jun 2021 15:33:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:40:19

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:40:19

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

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

What was the participant's randomization number? 142807

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 19:12:33

Generated On: 09 Jun 2021 15:33:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:37
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 15:58
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 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 19:12:33

Generated On: 09 Jun 2021 15:33:21

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 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 4 AUG 2020

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

Treatment Date and Time (derived) 4 AUG 2020 15:23

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 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	14:58 (24 HR)
Collection date and time (derived)	04 AUG 2020 14:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:50	04 AUG 2020 14:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 15:54

PC Open Date & Time

04 AUG 2020 15:43

PC Close Date & Time

04 AUG 2020 18:13

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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	04 AUG 2020 20:37
PC Open Date & Time	04 AUG 2020 19:08
PC Close Date & Time	05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 12:08

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 12:05

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 19:37

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:24

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 13:16

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

98.0 °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

10 AUG 2020 12:19

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 15:56

PC Open Date & Time

04 AUG 2020 15:43

PC Close Date & Time

04 AUG 2020 18:13

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 20:38

PC Open Date & Time

04 AUG 2020 19:08

PC Close Date & Time

05 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 12:09

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 12:06

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 19:38

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

08 AUG 2020 12:25

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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

09 AUG 2020 13:16

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

10 AUG 2020 12:19

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 15:57
PC Open Date & Time	04 AUG 2020 15:43
PC Close Date & Time	04 AUG 2020 18:13

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 20:38
PC Open Date & Time	04 AUG 2020 19:08
PC Close Date & Time	05 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

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)

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 12:10
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2315

EAB) (1725)

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

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 ☒

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:38
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

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 ☒

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EAB) (1725)

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US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:25
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 ☒

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 13:17
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:27
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

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)	01 SEP 2020
Time of assessment (00:00-23:59)	16:01 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 16:01
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3182158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 SEP 2020

What was the treatment time? (00:00-23:59) 15:26 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 15:26

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

US3182158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 SEP 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

01 SEP 2020 14:50

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	01 SEP 2020 14:42
Nasopharyngeal Swab 2	No		

US3182158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

98.5 °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

01 SEP 2020 15:56

PC Open Date & Time

01 SEP 2020 15:46

PC Close Date & Time

01 SEP 2020 18:16

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 97.7 °F

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

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

PC Time Stamp	01 SEP 2020 20:09
PC Open Date & Time	01 SEP 2020 19:11
PC Close Date & Time	02 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

02 SEP 2020 13:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

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

97.1 °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

06 SEP 2020 12:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

97.3 °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

07 SEP 2020 12:00

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

01 SEP 2020 15:57

PC Open Date & Time

01 SEP 2020 15:46

PC Close Date & Time

01 SEP 2020 18:16

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

01 SEP 2020 20:11

PC Open Date & Time

01 SEP 2020 19:11

PC Close Date & Time

02 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 13:24

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 12:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 15:57
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PC Open Date & Time	01 SEP 2020 15:46
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PC Close Date & Time	01 SEP 2020 18:16
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US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 20:11
PC Open Date & Time	01 SEP 2020 19:11
PC Close Date & Time	02 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 2315

EAB) (1725)

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:24
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

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 ☒

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2315

EAB) (1725)

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:17
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 ☒

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

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 ☒

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:17:54

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	14:44 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:44
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

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.

US3182158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

14:55 (24 HR)

Collection date and time (derived)

29 SEP 2020 14:55

US3182158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:12:33

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

07 OCT 2020 15:16:09

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 09:44:36

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 11:48:02

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 00:29:41

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 00:25:59
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 10:29:52

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 08:42:21

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

27 NOV 2020 18:01:08

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

03 DEC 2020 08:55:05

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

10 DEC 2020 08:14:55

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 06:32:01

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 07:36:52

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 08:37:25

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 08:30:04

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 15:59:48

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 07:00:49

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 07:37:20

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 11:17:04

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 17:50:00
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

18 FEB 2021 06:55:21

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 11:49:54

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 07:37:42

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 12:31:45

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

18 MAR 2021 07:45:12

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 MAR 2021 07:50:14
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 10:17:41

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 07:44:48

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

19 APR 2021 13:48:36

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 07:26:27

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 <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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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°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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 <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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 <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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 439

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

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

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

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

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

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

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐ 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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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°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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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°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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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°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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 MAR 2022 00:01

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28 MAR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 <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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 <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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 <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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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°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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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="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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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="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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 <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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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"/>

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Please contact your study clinic immediately. Click below to confirm that you have read this message 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 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3182158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:33:21

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		02 MAR 2021 12:08:28

US3182158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	VISIT4

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:53:55

Generated On: 09 Jun 2021 15:33:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3182158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

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.

US3182158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 11 Mar 2021 22:12:55

Generated On: 09 Jun 2021 15:33:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 FEB 2021
Collection time (00:00-23:59)	14:24 (24 HR)
Collection date and time (derived)	16 FEB 2021 14:24

US3182158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:23:48

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 15:46:52

Generated On: 09 Jun 2021 15:33:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3182158

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:46:52

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182158

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182158

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:33:21

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"/>

US3182158

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:33:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3182158

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3182158

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

Date of updated informed consent (dd MMM yyyy) 26 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 26 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

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

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00-23:59)	11:07 (24 HR)
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Collection date and time (derived)	26 JAN 2021 11:07
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US3182158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	10:48
Collection Date and Time (derived)	26 JAN 2021 10:48

US3182158

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

AEID	USA-US075-2021-MRNA-1273-P30 1000004
Adverse event	HERNIATED DISC
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	13 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

SUBJECT STARTED HAVING
NECK PAIN IN SEPTEMBER
2020, SAW DOCTOR IN
DECEMBER 2020. SCHEDULED
HERNIATED DISC REPAIR IN
JANUARY. SURGERY DATE
WAS 1/12/2021 AND SUBJECT
WAS HOSPITALIZED UNTIL
1/13/2021.

PER MEDICAL RECORDS,
SUBJECT DID NOT HAVE A
COVID-19 TEST PRIOR TO
PROCEDURE.

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

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

AEID

Adverse event

EXACERBATION OF NECK
SECONDARY TO PINCHED
NERVE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

AEID	USA-US075-2021-MRNA-1273-P30 1000011
Adverse event	DIFFICULTY BREATHING
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)	15 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	18 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

SUBJECT PRESENTED TO ER ON
1/16/2021 WITH COMPLAINTS OF
DIFFICULTY
BREATHING/SWALLOWING.
PATIENT HAD A C4 TO C6
ACDF ON 1/12/2021. SUBJECT
REPORTED BEGINNING ON
1/15/2021 HE BEGAN
INCREASING DYSPHASIA,
DIFFICULTY SWALLOWING
LIQUIDS AND DIFFICULTY
BREATHING. HE DID DENY ANY
SHORTNESS OF BREATH.
COVID NASAL SWAB
PERFORMED ON 1/16/2021,
RESULTS NEGATIVE. LAB TEST
PERFORMED: CBC: RBC=4.86,
WBC=7.8, MCV=80,
NEUTROPHILS= 58.3%) CMP
(NA+=139, CL-=104, BUN 9,
GLUCOSE= 106, K+=3.6,
HCO3-=21, CREATININE= 1.01,
TOTAL BILIRUBIN=0.4, AST=19,
ALT=23, ALK=53, CALCIUM=9.2,
ANION GAP=18, ALBUMIN=4.1,
TOTAL PROTEIN=6.7)
COAGULATION PANEL: PT=10.7
INR= 0.9, PTT=24L) TYPE AND
SCREEN. RESULTS OF LABS
WERE WITHIN NORMAL
LIMITS, UNITS NOT GIVEN.
IMAGING INCLUDED CHEST
X-RAY, CT PE, CT SCAN OF
NECK. CHEST X RAY SHOWED
NO ACUTE

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

CARDIOPULMONARY PROCESS,
CT PE SHOWED NO EVIDENCE
OF PULMONARY EMBOLISM.
CT SCAN OF THE NECK DID
SHOW CONCERN FOR
PREVERTEBRAL FLUID
COLLECTION EXTENDING
FROM C2-C5. THIS NOT APPEAR
TO BE INFECTIOUS.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

AEID	USA-US075-2021-MRNA-1273-P30 1000011
Adverse event	DYSPHASIA
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)	15 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	18 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

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

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

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

Yes ☒

No ☐

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

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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"/>

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication LAMOTRIGINE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER

Dose per administration 200

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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EAB) (1725)

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US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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 2007	
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)	2	
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 (4)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication TAMSULOSIN HCL

Prophylaxis Yes ☐
No ☒

Indication ENLARGED PROSTATE

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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 JUN 2019	
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 (6)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication EZETIMIBE

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 10000

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 (7)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (8)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication COENZYME Q10

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 300

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 (8)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2019	
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 (9)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication PREDNISONE DOSE PACK

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM PINCHED NERVE IN
NECK

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL
INFLAMMATION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (14)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY TO
ANTERIOR CERVICAL
DISCECTOMY

Dose per administration 325

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 (14)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☒
No ☐

Indication POST PROCEDURE
CONSTIPATION PROPHYLAXIS

Dose per administration 17

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 (15)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication POST PROCEDURE NAUSEA
PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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)		13 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY TO
ANTERIOR CERVICAL
DISCECTOMY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

367 of 2315

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2315

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 12:47:36

Generated On: 09 Jun 2021 15:33:21

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:23:47

Generated On: 09 Jun 2021 15:33:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 13:18:48

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 JAN 2021	ANTERIOR CERVICAL DISCECTOMY/DECOMPRESSION	Adverse Event	
16 JAN 2021	CBC PANEL	Diagnostic	
16 JAN 2021	CMP PANEL	Diagnostic	
16 JAN 2021	COAG PANEL	Diagnostic	
16 JAN 2021	TYPE AND SCREEN LABS	Diagnostic	
16 JAN 2021	CHEST X-RAY	Diagnostic	
16 JAN 2021	CT (PE)	Diagnostic	
16 JAN 2021	CT (NECK)	Diagnostic	
12 JAN 2021	X-RAY	Diagnostic	

US3182158

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:33:21

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 ☐

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 17:15:32

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	5

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 17:15:32

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	5
Date of submission (Pre-filled from custom function)	27/JAN/2021 18:11
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

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 17:15:32

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	5
Date of submission (Pre-filled from custom function)	23/FEB/2021 15:08
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

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 17:15:32

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	5
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 17:15:32

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 13:03
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

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 17:15:32

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 12:14
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

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000011
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)	2

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000011
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)	2
Date of submission (Pre-filled from custom function)	26/MAR/2021 13:07
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

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 15:31:21

Generated On: 09 Jun 2021 15:33:21

SAEID	USA-US075-2021-MRNA-1273-P301000011
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)	2
Date of submission (Pre-filled from custom function)	08/APR/2021 13:18
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

US3182158 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182158

Form: Participant Creation

Generated On: 09 Jun 2021 15:33:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'US3182158'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:10

US3182158

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	04 Aug 2020 19:25:10

US3182158

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:11

US3182158

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Clinic (Clinic)'	Brooke Glivar (b) (4)	04 Aug 2020 19:25:10

US3182158

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'SCRN'	System	04 Aug 2020 19:25:10

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:12

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '62'	(b) (4)	07 Aug 2020 22:11:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'YEARS'	System	07 Aug 2020 22:11:22

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '62'	System	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Male (M)'	Cassie Uminski (b) (4)	07 Aug 2020 22:11:22

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cassie Uminski (b) (4)	07 Aug 2020 22:11:22

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'I'	Cassie Uminski (b) (4)	07 Aug 2020 22:11:22

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:11:22

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4)	07 Aug 2020 22:11:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4)	07 Aug 2020 22:11:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4)	07 Aug 2020 22:11:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:11:22

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4)	07 Aug 2020 22:11:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4)	07 Aug 2020 22:11:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4)	07 Aug 2020 22:11:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '4 Aug 2020'	Brooke Glivar (b) (4)	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Aug 2020'	System	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '2020'	System	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Amendment 1 (1)'	Brooke Glivar (b) (4)	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	Brooke Glivar (b) (4)	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	Brooke Glivar (b) (4)	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	Brooke Glivar (b) (4)	04 Aug 2020 19:25:28

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:11

US3182158

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'I'	System	04 Aug 2020 19:25:34

US3182158

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	04 Aug 2020 19:25:34

US3182158

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:33:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:17:44

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:20:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:20:13
Data point term sent to Coder	System	07 Aug 2020 22:19:01
User entered 'Asthma'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 2000'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 2000'	System	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '2000'	System	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:18:07

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:20:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:20:13
Data point term sent to Coder	System	07 Aug 2020 22:19:01
User entered 'Seasonal allergies'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 1980'	Cassie Uminski	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4)	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 1980'	System	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '1980'	System	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:18:19

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Trophic disorders, PT: Dysplasia, LLT: Dysplasia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 09:09:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 09:09:22
Data point term sent to Coder	System	07 Aug 2020 22:19:02
User entered 'Right ventricle dysplasia'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 1999'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4)	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 1999'	System	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '1999'	System	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:18:38

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:20:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:20:40
Data point term sent to Coder	System	07 Aug 2020 22:19:01
User entered 'cardiac stents'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 2010'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Oct 2020 12:25:05
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 16:58:12
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	05 Oct 2020 16:58:08
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:43:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	05 Oct 2020 16:58:08
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:18:55
	(b) (4)	

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 2010'	System	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '2010'	System	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 2010'	System	05 Oct 2020 16:58:08
User entered empty.	System	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '2010'	System	05 Oct 2020 16:58:08
User entered empty.	System	07 Aug 2020 22:18:55

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:21:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:21:14
Data point term sent to Coder	System	07 Aug 2020 22:20:03
User entered 'High Cholesterol'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 1993'	Cassie Uminski	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4)	07 Aug 2020 22:19:05
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 1993'	System	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '1993'	System	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:19:05

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Respiratory and mediastinal neoplasms benign (excl mesotheliomas), HLT: Mediastinal neoplasms benign, PT: Benign neoplasm of thymus, LLT: Benign neoplasm of thymus - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:29:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:29:03
Data point term sent to Coder	System	07 Aug 2020 22:20:03
User entered 'Benign thynoma'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 1993'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:19:21
	(b) (4)	

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 1993'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 1993'	System	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '1993'	System	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 1993'	System	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '1993'	System	07 Aug 2020 22:19:21

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar II disorder, LLT: Bipolar II disorder - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:21:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:21:15
Data point term sent to Coder	System	07 Aug 2020 22:20:03
User entered 'Bipolar 2'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 2006'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 2006'	System	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '2006'	System	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:19:33

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:21:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:21:15
Data point term sent to Coder	System	07 Aug 2020 22:20:03
User entered 'Enlarged prostate'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'un UNK 2018'	Cassie Uminski	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	Cassie Uminski	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4)	07 Aug 2020 22:19:44
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 2018'	System	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '2018'	System	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Aug 2020 22:19:44

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 16:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 16:04:42
Data point term sent to Coder	System	07 Apr 2021 16:03:46
User entered 'Pinched Nerve in Neck'	Jennifer Gaston (b) (4)	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User entered 'un UNK 2018'	Jennifer Gaston (b) (4)	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'Jan 2018'	System	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '2018'	System	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered empty.	System	07 Apr 2021 16:02:59

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:12:22
	(b) (4)	

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '04 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '14:37'	(b) (4)	07 Aug 2020 22:12:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered '04 Aug 2020 14:37'	System	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '173.3' cm	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 22:12:22
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:25:34

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '90.0' kg	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 22:12:22
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:25:34

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
Amendment Manager: User entered '29.96715'	System	16 Sep 2020 23:42:56
User entered '30.0'	System	07 Aug 2020 22:12:22
DataPoint set to visible.	System	04 Aug 2020 19:25:34

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'kg/m2'	System	07 Aug 2020 22:12:22
DataPoint set to visible.	System	04 Aug 2020 19:25:34

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
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)	06 Oct 2020 18:39:17
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 18:52:25
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	29 Sep 2020 18:52:17
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 05:01:23
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	29 Sep 2020 18:52:17
	(b) (4)	
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:12:22
	(b) (4)	

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'bpm'	System	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'breaths/min'	System	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'mmHg'	System	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User entered 'mmHg'	System	07 Aug 2020 22:12:22

US3182158

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59

US3182158

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:14:33
	(b) (4)	

US3182158

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:39:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 13:43:43
User entered '04 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:14:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	(b) (4)	07 Aug 2020 22:15:46
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

[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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	(b) (4)	07 Aug 2020 22:15:46
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:15:46

US3182158

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'No (N)'	(b) (4)	07 Aug 2020 22:15:46
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4)	07 Aug 2020 22:15:46
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered 'I'	(b) (4)	07 Aug 2020 22:15:46
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

US3182158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

[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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:46

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:15:46

US3182158

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered '0'	(b) (4)	07 Aug 2020 22:15:46
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:19:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:19
User entered empty.	(b) (4)	07 Aug 2020 22:15:46
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	07 Aug 2020 22:15:20

US3182158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '04 Aug 2020'	Cassie Uminski	07 Aug 2020 22:15:20

US3182158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[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 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:20

US3182158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'VISIT1'	System	07 Aug 2020 22:15:20

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:14:33

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:03:25
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:03:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:14:33
User entered '142807' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:14:33

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:14:33

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

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 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:14:23
	(b) (4)	

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

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 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 22:14:23

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	Cassie Uminski (b) (4)	07 Aug 2020 22:14:23

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	Cassie Uminski	07 Aug 2020 22:14:23

US3182158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	Cassie Uminski	07 Aug 2020 22:14:23

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '04 Aug 2020'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:37'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '04 Aug 2020 14:37'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '98.0' F	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '67'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'bpm'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '16'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'breaths/min'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '124'	Cassie Uminski	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '82'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '04 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:53:58
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 22:13:14
User entered '15:58'	Cassie Uminski (b) (4) (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '04 Aug 2020 15:58'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '98.2' F	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Oral (Oral)'	Cassie Uminski	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	(b) (4)	07 Aug 2020 22:13:14
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '61'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14
	(b) (4)	

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'bpm'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '16'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'breaths/min'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '127'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '86'	Cassie Uminski (b) (4)	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	07 Aug 2020 22:13:14

US3182158

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	07 Aug 2020 22:14:37
	(b) (4)	

US3182158

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 22:14:37

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Brooke Glivar (b) (4)	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Brooke Glivar (b) (4)	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '4 Aug 2020'	Brooke Glivar (b) (4)	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '15:23'	Brooke Glivar (b) (4)	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '4 Aug 2020 15:23'	System	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Left Arm (LEFT ARM)'	Brooke Glivar (b) (4)	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'ONCE'	System	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 19:26:18

US3182158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:05

US3182158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '04 Aug 2020'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:05

US3182158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:58'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:05

US3182158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '04 Aug 2020 14:58'	System	07 Aug 2020 22:15:05

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '04 Aug 2020'	Cassie Uminski (b) (4)	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	07 Aug 2020 22:14:49
	(b) (4)	

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:50'	Cassie Uminski (b) (4)	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '04 Aug 2020 14:50'	System	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	Cassie Uminski	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Cassie Uminski (b) (4)	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered empty.	System	07 Aug 2020 22:14:49

US3182158

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Aug 2020 22:15:11

US3182158

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	07 Aug 2020 22:15:11

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:51:33', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0fc7a510-ee50-48ac-b777-e3049372dba5'	System	04 Aug 2020 19:54:33
User entered 'Yes (Y)'	System	04 Aug 2020 19:54:33

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:54:17', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0fc7a510-ee50-48ac-b777-e3049372dba5'	System	04 Aug 2020 19:54:33
User entered '98.2'	System	04 Aug 2020 19:54:33

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:54:22', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0fc7a510-ee50-48ac-b777-e3049372dba5'	System	04 Aug 2020 19:54:33
User entered 'No (N)'	System	04 Aug 2020 19:54:33

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:54:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0fc7a510-ee50-48ac-b777-e3049372dba5'	System	04 Aug 2020 19:54:33
User entered '04 Aug 2020 15:54'	System	04 Aug 2020 19:54:33

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 15:43'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 18:13'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:36:24', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4ec7f88a-8580-481f-8b34-35965c185e08'	System	05 Aug 2020 00:37:19
User entered 'Yes (Y)'	System	05 Aug 2020 00:37:19

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:37:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4ec7f88a-8580-481f-8b34-35965c185e08'	System	05 Aug 2020 00:37:19
User entered '98.0'	System	05 Aug 2020 00:37:19

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:37:10', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4ec7f88a-8580-481f-8b34-35965c185e08'	System	05 Aug 2020 00:37:19
User entered 'No (N)'	System	05 Aug 2020 00:37:19

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:37:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4ec7f88a-8580-481f-8b34-35965c185e08'	System	05 Aug 2020 00:37:19
User entered '04 Aug 2020 20:37'	System	05 Aug 2020 00:37:19

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 19:08'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 2'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:07:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '626a0fd3-3f2d-4282-9ba1-c5acca3d2fc'	System	05 Aug 2020 16:08:18
User entered 'Yes (Y)'	System	05 Aug 2020 16:08:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:08:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '626a0fd3-3f2d-4282-9ba1-c5acca3d2fc'	System	05 Aug 2020 16:08:18
User entered '97.8'	System	05 Aug 2020 16:08:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:08:09', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '626a0fd3-3f2d-4282-9ba1-c5acca3d2fc'	System	05 Aug 2020 16:08:18
User entered 'No (N)'	System	05 Aug 2020 16:08:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:08:14', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '626a0fd3-3f2d-4282-9ba1-c5accca3d2fc'	System	05 Aug 2020 16:08:18
User entered '05 Aug 2020 12:08'	System	05 Aug 2020 16:08:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 3'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:05:32', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bc9b4336-7e4d-49f8-84c3-a1595e2ee763'	System	06 Aug 2020 16:05:50
User entered 'Yes (Y)'	System	06 Aug 2020 16:05:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:05:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bc9b4336-7e4d-49f8-84c3-a1595e2ee763'	System	06 Aug 2020 16:05:50
User entered '97.6'	System	06 Aug 2020 16:05:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:05:43', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bc9b4336-7e4d-49f8-84c3-a1595e2ee763'	System	06 Aug 2020 16:05:50
User entered 'No (N)'	System	06 Aug 2020 16:05:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:05:48', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bc9b4336-7e4d-49f8-84c3-a1595e2ee763'	System	06 Aug 2020 16:05:50
User entered '06 Aug 2020 12:05'	System	06 Aug 2020 16:05:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 4'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:37:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'b2c661e6-8693-481f-b89d-96b821a65231'	System	07 Aug 2020 23:37:49
User entered 'Yes (Y)'	System	07 Aug 2020 23:37:49

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:37:37', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'b2c661e6-8693-481f-b89d-96b821a65231' User entered '97.4'	System	07 Aug 2020 23:37:49
	System	07 Aug 2020 23:37:49

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:37:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'b2c661e6-8693-481f-b89d-96b821a65231'	System	07 Aug 2020 23:37:49
User entered 'No (N)'	System	07 Aug 2020 23:37:49

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:37:44', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'b2c661e6-8693-481f-b89d-96b821a65231' User entered '07 Aug 2020 19:37'	System	07 Aug 2020 23:37:49
	System	07 Aug 2020 23:37:49

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 5'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:24:33', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '076f061b-1e32-4d6a-9439-972d13204b7c'	System	08 Aug 2020 16:24:50
User entered 'Yes (Y)'	System	08 Aug 2020 16:24:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:24:41', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '076f061b-1e32-4d6a-9439-972d13204b7c'	System	08 Aug 2020 16:24:50
User entered '96.4'	System	08 Aug 2020 16:24:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:24:44', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '076f061b-1e32-4d6a-9439-972d13204b7c'	System	08 Aug 2020 16:24:50
User entered 'No (N)'	System	08 Aug 2020 16:24:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:24:48', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '076f061b-1e32-4d6a-9439-972d13204b7c'	System	08 Aug 2020 16:24:50
User entered '08 Aug 2020 12:24'	System	08 Aug 2020 16:24:50

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 6'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:15:55', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'faa6bee7-b0e3-448d-9372-974e2b972216'	System	09 Aug 2020 17:16:12
User entered 'Yes (Y)'	System	09 Aug 2020 17:16:12

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'faa6bee7-b0e3-448d-9372-974e2b972216'	System	09 Aug 2020 17:16:12
User entered '98.3'	System	09 Aug 2020 17:16:12

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'faa6bee7-b0e3-448d-9372-974e2b972216'	System	09 Aug 2020 17:16:12
User entered 'No (N)'	System	09 Aug 2020 17:16:12

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:10', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'faa6bee7-b0e3-448d-9372-974e2b972216'	System	09 Aug 2020 17:16:12
User entered '09 Aug 2020 13:16'	System	09 Aug 2020 17:16:12

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 7'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '136aafe3-8149-4976-a05e-79741988cd9a'	System	10 Aug 2020 16:19:21
User entered 'Yes (Y)'	System	10 Aug 2020 16:19:21

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:12', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '136aafe3-8149-4976-a05e-79741988cd9a'	System	10 Aug 2020 16:19:21
User entered '98.0'	System	10 Aug 2020 16:19:21

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:15', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '136aafe3-8149-4976-a05e-79741988cd9a'	System	10 Aug 2020 16:19:21
User entered 'No (N)'	System	10 Aug 2020 16:19:21

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:19', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '136aafe3-8149-4976-a05e-79741988cd9a'	System	10 Aug 2020 16:19:21
User entered '10 Aug 2020 12:19'	System	10 Aug 2020 16:19:21

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:55:24', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '78f665fe-ed11-4a94-a1b8-ec732f53c726'	System	04 Aug 2020 19:56:56
User entered 'None (1)'	System	04 Aug 2020 19:56:56

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:55:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '78f665fe-ed11-4a94-a1b8-ec732f53c726'	System	04 Aug 2020 19:56:56
User entered 'Yes (Y)'	System	04 Aug 2020 19:56:56

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:56:23', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '78f665fe-ed11-4a94-a1b8-ec732f53c726'	System	04 Aug 2020 19:56:56
User entered '10'	System	04 Aug 2020 19:56:56

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:56:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '78f665fe-ed11-4a94-a1b8-ec732f53c726'	System	04 Aug 2020 19:56:56
User entered 'No (N)'	System	04 Aug 2020 19:56:56

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:56:42', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '78f665fe-ed11-4a94-a1b8-ec732f53c726'	System	04 Aug 2020 19:56:56
User entered 'None (1)'	System	04 Aug 2020 19:56:56

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:56:51', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '78f665fe-ed11-4a94-a1b8-ec732f53c726'	System	04 Aug 2020 19:56:56
User entered '04 Aug 2020 15:56'	System	04 Aug 2020 19:56:56

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 15:43'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 18:13'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:37:47', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4077d6ca-17d4-4a09-a6f0-0393e9fb35d7'	System	05 Aug 2020 00:38:10
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 00:38:10

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:37:42', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4077d6ca-17d4-4a09-a6f0-0393e9fb35d7'	System	05 Aug 2020 00:38:10
User entered 'No (N)'	System	05 Aug 2020 00:38:10

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:37:50', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4077d6ca-17d4-4a09-a6f0-0393e9fb35d7'	System	05 Aug 2020 00:38:10
User entered 'No (N)'	System	05 Aug 2020 00:38:10

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4077d6ca-17d4-4a09-a6f0-0393e9fb35d7'	System	05 Aug 2020 00:38:10
User entered 'None (1)'	System	05 Aug 2020 00:38:10

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4077d6ca-17d4-4a09-a6f0-0393e9fb35d7'	System	05 Aug 2020 00:38:10
User entered '04 Aug 2020 20:38'	System	05 Aug 2020 00:38:10

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 19:08'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 2'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:08:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'c25d9cb9-facb-43f0-965f-8314594d8f11'	System	05 Aug 2020 16:09:27
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 16:09:27

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:08:28', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'c25d9cb9-facb-43f0-965f-8314594d8f11'	System	05 Aug 2020 16:09:27
User entered 'No (N)'	System	05 Aug 2020 16:09:27

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:08:53', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'c25d9cb9-facb-43f0-965f-8314594d8f11'	System	05 Aug 2020 16:09:27
User entered 'No (N)'	System	05 Aug 2020 16:09:27

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:09:19', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'c25d9cb9-facb-43f0-965f-8314594d8f11'	System	05 Aug 2020 16:09:27
User entered 'None (1)'	System	05 Aug 2020 16:09:27

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:09:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'c25d9cb9-facb-43f0-965f-8314594d8f11'	System	05 Aug 2020 16:09:27
User entered '05 Aug 2020 12:09'	System	05 Aug 2020 16:09:27

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 3'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:05:59', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '93e9a3ff-4289-42ec-8eb4-c6bad46c59e8'	System	06 Aug 2020 16:06:32
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 16:06:32

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '93e9a3ff-4289-42ec-8eb4-c6bad46c59e8'	System	06 Aug 2020 16:06:32
User entered 'No (N)'	System	06 Aug 2020 16:06:32

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '93e9a3ff-4289-42ec-8eb4-c6bad46c59e8'	System	06 Aug 2020 16:06:32
User entered 'No (N)'	System	06 Aug 2020 16:06:32

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '93e9a3ff-4289-42ec-8eb4-c6bad46c59e8'	System	06 Aug 2020 16:06:32
User entered 'None (1)'	System	06 Aug 2020 16:06:32

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '93e9a3ff-4289-42ec-8eb4-c6bad46c59e8'	System	06 Aug 2020 16:06:32
User entered '06 Aug 2020 12:06'	System	06 Aug 2020 16:06:32

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 4'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:37:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2ab33a4f-1810-42ff-a8be-f4b777e747c2'	System	07 Aug 2020 23:38:07
User entered 'None (1)'	System	07 Aug 2020 23:38:07

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:37:54', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2ab33a4f-1810-42ff-a8be-f4b777e747c2'	System	07 Aug 2020 23:38:07
User entered 'No (N)'	System	07 Aug 2020 23:38:07

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:37:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2ab33a4f-1810-42ff-a8be-f4b777e747c2'	System	07 Aug 2020 23:38:07
User entered 'No (N)'	System	07 Aug 2020 23:38:07

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2ab33a4f-1810-42ff-a8be-f4b777e747c2'	System	07 Aug 2020 23:38:07
User entered 'None (1)'	System	07 Aug 2020 23:38:07

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:04', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2ab33a4f-1810-42ff-a8be-f4b777e747c2'	System	07 Aug 2020 23:38:07
User entered '07 Aug 2020 19:38'	System	07 Aug 2020 23:38:07

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 5'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:24:54', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '66994d87-f857-48b1-9137-b37ee52fa3c8'	System	08 Aug 2020 16:25:09
User entered 'None (1)'	System	08 Aug 2020 16:25:09

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:24:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '66994d87-f857-48b1-9137-b37ee52fa3c8'	System	08 Aug 2020 16:25:09
User entered 'No (N)'	System	08 Aug 2020 16:25:09

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '66994d87-f857-48b1-9137-b37ee52fa3c8'	System	08 Aug 2020 16:25:09
User entered 'No (N)'	System	08 Aug 2020 16:25:09

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:04', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '66994d87-f857-48b1-9137-b37ee52fa3c8'	System	08 Aug 2020 16:25:09
User entered 'None (1)'	System	08 Aug 2020 16:25:09

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '66994d87-f857-48b1-9137-b37ee52fa3c8'	System	08 Aug 2020 16:25:09
User entered '08 Aug 2020 12:25'	System	08 Aug 2020 16:25:09

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 6'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4fc8c638-3ad7-4a55-9890-5abfbe5c407b'	System	09 Aug 2020 17:16:40
User entered 'None (1)'	System	09 Aug 2020 17:16:40

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4fc8c638-3ad7-4a55-9890-5abfbe5c407b'	System	09 Aug 2020 17:16:40
User entered 'No (N)'	System	09 Aug 2020 17:16:40

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4fc8c638-3ad7-4a55-9890-5abfbe5c407b'	System	09 Aug 2020 17:16:40
User entered 'No (N)'	System	09 Aug 2020 17:16:40

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:34', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4fc8c638-3ad7-4a55-9890-5abfbe5c407b'	System	09 Aug 2020 17:16:40
User entered 'None (1)'	System	09 Aug 2020 17:16:40

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:38', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '4fc8c638-3ad7-4a55-9890-5abfbe5c407b'	System	09 Aug 2020 17:16:40
User entered '09 Aug 2020 13:16'	System	09 Aug 2020 17:16:40

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 7'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:24', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bf240b8a-ee1e-4aea-8295-8ac891cc9b30'	System	10 Aug 2020 16:19:38
User entered 'None (1)'	System	10 Aug 2020 16:19:38

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bf240b8a-ee1e-4aea-8295-8ac891cc9b30'	System	10 Aug 2020 16:19:38
User entered 'No (N)'	System	10 Aug 2020 16:19:38

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:29', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bf240b8a-ee1e-4aea-8295-8ac891cc9b30'	System	10 Aug 2020 16:19:38
User entered 'No (N)'	System	10 Aug 2020 16:19:38

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:32', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bf240b8a-ee1e-4aea-8295-8ac891cc9b30'	System	10 Aug 2020 16:19:38
User entered 'None (1)'	System	10 Aug 2020 16:19:38

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:36', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bf240b8a-ee1e-4aea-8295-8ac891cc9b30'	System	10 Aug 2020 16:19:38
User entered '10 Aug 2020 12:19'	System	10 Aug 2020 16:19:38

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:56:58', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered 'None (0)'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:57:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered 'None (0)'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:57:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered 'None (0)'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:57:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered 'None (0)'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:57:11', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered 'None (0)'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:57:13', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered 'None (0)'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:57:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered 'No (N)'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T15:57:21', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9080bba8-52e0-47dd-a0e7-37bfb57b57f7'	System	04 Aug 2020 19:57:22
User entered '04 Aug 2020 15:57'	System	04 Aug 2020 19:57:22

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 15:43'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 18:13'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:14', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered 'None (0)'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:18', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered 'None (0)'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:21', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered 'None (0)'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:24', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered 'None (0)'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered 'None (0)'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered 'None (0)'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:34', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered 'No (N)'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-04T20:38:39', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'dc4d5dd5-488b-4018-83dc-90ec22beddb5'	System	05 Aug 2020 00:38:42
User entered '04 Aug 2020 20:38'	System	05 Aug 2020 00:38:42

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Aug 2020 19:08'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 2'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:09:31', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered 'None (0)'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:09:48', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered 'No interference with activity (1)'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:09:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered 'None (0)'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:10:04', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered 'None (0)'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:10:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered 'None (0)'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:10:10', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered 'None (0)'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:10:14', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered 'No (N)'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-05T12:10:22', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '995b7919-9a38-40f6-be13-ff13443ded1d'	System	05 Aug 2020 16:10:23
User entered '05 Aug 2020 12:10'	System	05 Aug 2020 16:10:23

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 3'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:36', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered 'None (0)'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered 'None (0)'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:43', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered 'None (0)'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:47', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered 'None (0)'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:54', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered 'None (0)'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:06:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered 'None (0)'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:07:01', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered 'No (N)'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-06T12:07:07', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'deb7eead-159b-4006-a6b4-841bfb68d610'	System	06 Aug 2020 16:07:08
User entered '06 Aug 2020 12:07'	System	06 Aug 2020 16:07:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 4'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:09', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered 'None (0)'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:12', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered 'None (0)'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:14', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered 'None (0)'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:18', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered 'None (0)'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:20', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered 'None (0)'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:23', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered 'None (0)'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:26', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered 'No (N)'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-07T19:38:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '76e86c4b-faae-4480-8d79-fc3808bd1b9c'	System	07 Aug 2020 23:38:32
User entered '07 Aug 2020 19:38'	System	07 Aug 2020 23:38:32

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 5'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:13', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered 'None (0)'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered 'None (0)'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:18', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered 'None (0)'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:21', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered 'None (0)'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:24', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered 'None (0)'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered 'None (0)'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:34', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered 'No (N)'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-08T12:25:38', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f8c4a853-49bf-465f-aad8-62394d60893f'	System	08 Aug 2020 16:25:40
User entered '08 Aug 2020 12:25'	System	08 Aug 2020 16:25:40

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 6'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:44', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f'	System	09 Aug 2020 17:17:09
User entered 'None (0)'	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:47', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f' User entered 'None (0)'	System	09 Aug 2020 17:17:09
	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:49', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f' User entered 'None (0)'	System	09 Aug 2020 17:17:09
	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f' User entered 'None (0)'	System	09 Aug 2020 17:17:09
	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:54', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f' User entered 'None (0)'	System	09 Aug 2020 17:17:09
	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:16:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f' User entered 'None (0)'	System	09 Aug 2020 17:17:09
	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:17:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f'	System	09 Aug 2020 17:17:09
User entered 'No (N)'	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-09T13:17:04', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a35dd8d1-6b25-4d09-8f7e-5218f3cb318f' User entered '09 Aug 2020 13:17'	System	09 Aug 2020 17:17:09
	System	09 Aug 2020 17:17:09

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 7'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered 'None (0)'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:42', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered 'None (0)'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:44', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered 'None (0)'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:47', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered 'None (0)'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:49', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered 'None (0)'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:19:51', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered 'None (0)'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:20:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered 'No (N)'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-08-10T12:20:06', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'af614143-cc08-428e-8685-c5362115c77f'	System	10 Aug 2020 16:20:08
User entered '10 Aug 2020 12:20'	System	10 Aug 2020 16:20:08

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 19:26:18

US3182158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:36:18

US3182158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered '11 Aug 2020'	Alec Ireland (b) (4)	20 Aug 2020 14:36:18

US3182158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	20 Aug 2020 14:36:18

US3182158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:36:18

US3182158

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:36:25

US3182158

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	20 Aug 2020 14:36:25

US3182158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:41:59

US3182158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered '18 Aug 2020'	Alec Ireland (b) (4)	24 Aug 2020 13:41:59

US3182158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:41:59

US3182158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:41:59

US3182158

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:41:45

US3182158

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	24 Aug 2020 13:41:45

US3182158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:17:49

US3182158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered '25 Aug 2020'	Alec Ireland (b) (4)	26 Aug 2020 18:17:49

US3182158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	26 Aug 2020 18:17:49

US3182158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:17:49

US3182158

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:17:41

US3182158

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	26 Aug 2020 18:17:41

US3182158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	03 Sep 2020 13:43:43

US3182158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 13:43:43

US3182158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[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 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	03 Sep 2020 13:43:43

US3182158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'VISIT2'	System	03 Sep 2020 13:43:43

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28
	(b) (4)	

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:27'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '01 Sep 2020 14:27'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '98.2' F	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	(b) (4)	03 Sep 2020 13:44:28
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '76'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'bpm'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'breaths/min'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '124'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '86'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '16:01'	(b) (4)	03 Sep 2020 13:44:28
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '01 Sep 2020 16:01'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '98.5' F	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '67'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'bpm'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '16'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'breaths/min'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '142'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '83'	Cassie Uminski (b) (4)	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	03 Sep 2020 13:44:28

US3182158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:46

US3182158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:46

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	(b) (4)	
	Amy Maroun (b) (4)	01 Sep 2020 19:34:05
	(b) (4)	

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '1 Sep 2020'	(b) (4) Amy Maroun (b) (4) (b) (4)	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '15:26'	(b) (4) Amy Maroun (b) (4) (b) (4)	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '1 Sep 2020 15:26'	System	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Left Arm (LEFT ARM)'	Amy Maroun (b) (4)	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'ONCE'	System	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 19:34:05

US3182158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	03 Sep 2020 13:58:39

US3182158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:39

US3182158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:50'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:39

US3182158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '01 Sep 2020 14:50'	System	03 Sep 2020 13:58:39

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '01 Sep 2020'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:17
	(b) (4)	

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:42'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '01 Sep 2020 14:42'	System	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Cassie Uminski (b) (4)	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered empty.	System	03 Sep 2020 13:58:17

US3182158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	03 Sep 2020 13:58:50

US3182158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	03 Sep 2020 13:58:50

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:56:29', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '573aa108-7ec7-4dc9-9a32-76ea0e44b5e6'	System	01 Sep 2020 19:56:48
User entered 'Yes (Y)'	System	01 Sep 2020 19:56:48

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:56:36', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '573aa108-7ec7-4dc9-9a32-76ea0e44b5e6' User entered '98.5'	System	01 Sep 2020 19:56:48
	System	01 Sep 2020 19:56:48

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:56:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '573aa108-7ec7-4dc9-9a32-76ea0e44b5e6'	System	01 Sep 2020 19:56:48
User entered 'No (N)'	System	01 Sep 2020 19:56:48

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:56:45', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '573aa108-7ec7-4dc9-9a32-76ea0e44b5e6'	System	01 Sep 2020 19:56:48
User entered '01 Sep 2020 15:56'	System	01 Sep 2020 19:56:48

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 15:46'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 18:16'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:09:34', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a99f46d-446f-4152-8e19-e2610dffe43c'	System	02 Sep 2020 00:09:55
User entered 'Yes (Y)'	System	02 Sep 2020 00:09:55

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:09:41', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a99f46d-446f-4152-8e19-e2610dffe43c'	System	02 Sep 2020 00:09:55
User entered '97.7'	System	02 Sep 2020 00:09:55

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:09:46', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a99f46d-446f-4152-8e19-e2610dffe43c'	System	02 Sep 2020 00:09:55
User entered 'No (N)'	System	02 Sep 2020 00:09:55

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:09:51', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a99f46d-446f-4152-8e19-e2610dffe43c'	System	02 Sep 2020 00:09:55
User entered '01 Sep 2020 20:09'	System	02 Sep 2020 00:09:55

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 19:11'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 2'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:23:13', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0265cfe1-2698-46f7-90ef-b55d0e155923'	System	02 Sep 2020 17:23:27
User entered 'Yes (Y)'	System	02 Sep 2020 17:23:27

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:23:18', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0265cfe1-2698-46f7-90ef-b55d0e155923' User entered '98.1'	System	02 Sep 2020 17:23:27
	System	02 Sep 2020 17:23:27

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:23:21', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0265cfe1-2698-46f7-90ef-b55d0e155923'	System	02 Sep 2020 17:23:27
User entered 'No (N)'	System	02 Sep 2020 17:23:27

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:23:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0265cfe1-2698-46f7-90ef-b55d0e155923'	System	02 Sep 2020 17:23:27
User entered '02 Sep 2020 13:23'	System	02 Sep 2020 17:23:27

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 3'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7e2c6d35-8ca9-4b8d-b65b-c1392c2264dc'	System	03 Sep 2020 16:31:47
User entered 'Yes (Y)'	System	03 Sep 2020 16:31:47

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:38', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7e2c6d35-8ca9-4b8d-b65b-c1392c2264dc'	System	03 Sep 2020 16:31:47
User entered '97.6'	System	03 Sep 2020 16:31:47

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:41', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7e2c6d35-8ca9-4b8d-b65b-c1392c2264dc'	System	03 Sep 2020 16:31:47
User entered 'No (N)'	System	03 Sep 2020 16:31:47

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:44', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7e2c6d35-8ca9-4b8d-b65b-c1392c2264dc'	System	03 Sep 2020 16:31:47
User entered '03 Sep 2020 12:31'	System	03 Sep 2020 16:31:47

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 4'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:01:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'e9a345f7-8145-41e9-9a7b-3dbaa17ec4df'	System	04 Sep 2020 16:03:23
User entered 'Yes (Y)'	System	04 Sep 2020 16:03:23

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:01:45', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'e9a345f7-8145-41e9-9a7b-3dbaa17ec4df' User entered '98.4'	System	04 Sep 2020 16:03:23
	System	04 Sep 2020 16:03:23

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:01:48', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'e9a345f7-8145-41e9-9a7b-3dbaa17ec4df'	System	04 Sep 2020 16:03:23
User entered 'No (N)'	System	04 Sep 2020 16:03:23

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:01:51', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'e9a345f7-8145-41e9-9a7b-3dbaa17ec4df' User entered '04 Sep 2020 12:01'	System	04 Sep 2020 16:03:23
	System	04 Sep 2020 16:03:23

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 5'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '39aebb15-0830-42db-a539-d2ca2737779a'	System	05 Sep 2020 16:16:30
User entered 'Yes (Y)'	System	05 Sep 2020 16:16:30

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:23', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '39aebb15-0830-42db-a539-d2ca2737779a' User entered '97.0'	System	05 Sep 2020 16:16:30
	System	05 Sep 2020 16:16:30

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:26', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '39aebb15-0830-42db-a539-d2ca2737779a'	System	05 Sep 2020 16:16:30
User entered 'No (N)'	System	05 Sep 2020 16:16:30

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:29', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '39aebb15-0830-42db-a539-d2ca2737779a' User entered '05 Sep 2020 12:16'	System	05 Sep 2020 16:16:30
	System	05 Sep 2020 16:16:30

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 6'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:00:56', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7f39f22b-4189-43d2-9b4d-3e02fd3fc1c0'	System	06 Sep 2020 16:01:37
User entered 'Yes (Y)'	System	06 Sep 2020 16:01:37

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:03', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7f39f22b-4189-43d2-9b4d-3e02fd3fc1c0'	System	06 Sep 2020 16:01:37
User entered '97.1'	System	06 Sep 2020 16:01:37

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7f39f22b-4189-43d2-9b4d-3e02fd3fc1c0'	System	06 Sep 2020 16:01:37
User entered 'No (N)'	System	06 Sep 2020 16:01:37

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '7f39f22b-4189-43d2-9b4d-3e02fd3fc1c0'	System	06 Sep 2020 16:01:37
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 16:01:37

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 7'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:00:39', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '5529929b-f130-4bab-a327-161b16ef373b'	System	07 Sep 2020 16:01:17
User entered 'Yes (Y)'	System	07 Sep 2020 16:01:17

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:00:47', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '5529929b-f130-4bab-a327-161b16ef373b' User entered '97.3'	System	07 Sep 2020 16:01:17
	System	07 Sep 2020 16:01:17

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:00:49', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '5529929b-f130-4bab-a327-161b16ef373b'	System	07 Sep 2020 16:01:17
User entered 'No (N)'	System	07 Sep 2020 16:01:17

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:00:53', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '5529929b-f130-4bab-a327-161b16ef373b'	System	07 Sep 2020 16:01:17
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 16:01:17

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f0b5920b-3f9f-40c6-8aab-0d259f9cfa09'	System	01 Sep 2020 19:57:23
User entered 'None (1)'	System	01 Sep 2020 19:57:23

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f0b5920b-3f9f-40c6-8aab-0d259f9cfa09'	System	01 Sep 2020 19:57:23
User entered 'No (N)'	System	01 Sep 2020 19:57:23

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:13', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f0b5920b-3f9f-40c6-8aab-0d259f9cfa09'	System	01 Sep 2020 19:57:23
User entered 'No (N)'	System	01 Sep 2020 19:57:23

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f0b5920b-3f9f-40c6-8aab-0d259f9cfa09'	System	01 Sep 2020 19:57:23
User entered 'None (1)'	System	01 Sep 2020 19:57:23

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:20', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f0b5920b-3f9f-40c6-8aab-0d259f9cfa09'	System	01 Sep 2020 19:57:23
User entered '01 Sep 2020 15:57'	System	01 Sep 2020 19:57:23

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 15:46'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 18:16'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:10:46', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '05efdc38-0a5a-4366-99a7-9b8478ec958c'	System	02 Sep 2020 00:11:04
User entered 'None (1)'	System	02 Sep 2020 00:11:04

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:10:51', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '05efdc38-0a5a-4366-99a7-9b8478ec958c'	System	02 Sep 2020 00:11:04
User entered 'No (N)'	System	02 Sep 2020 00:11:04

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:10:55', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '05efdc38-0a5a-4366-99a7-9b8478ec958c'	System	02 Sep 2020 00:11:04
User entered 'No (N)'	System	02 Sep 2020 00:11:04

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:10:58', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '05efdc38-0a5a-4366-99a7-9b8478ec958c'	System	02 Sep 2020 00:11:04
User entered 'None (1)'	System	02 Sep 2020 00:11:04

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:01', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '05efdc38-0a5a-4366-99a7-9b8478ec958c'	System	02 Sep 2020 00:11:04
User entered '01 Sep 2020 20:11'	System	02 Sep 2020 00:11:04

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 19:11'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 2'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:23:31', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f220e8e-d91d-4e32-b99b-7cf270a81e82'	System	02 Sep 2020 17:24:15
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 17:24:15

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:23:34', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f220e8e-d91d-4e32-b99b-7cf270a81e82'	System	02 Sep 2020 17:24:15
User entered 'No (N)'	System	02 Sep 2020 17:24:15

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f220e8e-d91d-4e32-b99b-7cf270a81e82'	System	02 Sep 2020 17:24:15
User entered 'No (N)'	System	02 Sep 2020 17:24:15

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:06', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f220e8e-d91d-4e32-b99b-7cf270a81e82'	System	02 Sep 2020 17:24:15
User entered 'None (1)'	System	02 Sep 2020 17:24:15

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:10', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f220e8e-d91d-4e32-b99b-7cf270a81e82'	System	02 Sep 2020 17:24:15
User entered '02 Sep 2020 13:24'	System	02 Sep 2020 17:24:15

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 3'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:51', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a68d9f81-c0e4-4964-b730-c3010804f8de'	System	03 Sep 2020 16:32:06
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:32:06

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:53', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a68d9f81-c0e4-4964-b730-c3010804f8de'	System	03 Sep 2020 16:32:06
User entered 'No (N)'	System	03 Sep 2020 16:32:06

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:56', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a68d9f81-c0e4-4964-b730-c3010804f8de'	System	03 Sep 2020 16:32:06
User entered 'No (N)'	System	03 Sep 2020 16:32:06

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:31:58', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a68d9f81-c0e4-4964-b730-c3010804f8de'	System	03 Sep 2020 16:32:06
User entered 'None (1)'	System	03 Sep 2020 16:32:06

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a68d9f81-c0e4-4964-b730-c3010804f8de'	System	03 Sep 2020 16:32:06
User entered '03 Sep 2020 12:32'	System	03 Sep 2020 16:32:06

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 4'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:01:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bd9e30ab-e110-4c43-b561-b8f75f408108'	System	04 Sep 2020 16:04:03
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 16:04:03

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:02:01', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bd9e30ab-e110-4c43-b561-b8f75f408108'	System	04 Sep 2020 16:04:03
User entered 'No (N)'	System	04 Sep 2020 16:04:03

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:02:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bd9e30ab-e110-4c43-b561-b8f75f408108'	System	04 Sep 2020 16:04:03
User entered 'No (N)'	System	04 Sep 2020 16:04:03

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:02:15', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bd9e30ab-e110-4c43-b561-b8f75f408108'	System	04 Sep 2020 16:04:03
User entered 'None (1)'	System	04 Sep 2020 16:04:03

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:02:18', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bd9e30ab-e110-4c43-b561-b8f75f408108'	System	04 Sep 2020 16:04:03
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:04:03

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 5'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:33', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bcd83f03-adb5-49ac-90db-b4d4d581e68d'	System	05 Sep 2020 16:16:46
User entered 'None (1)'	System	05 Sep 2020 16:16:46

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:36', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bcd83f03-adb5-49ac-90db-b4d4d581e68d'	System	05 Sep 2020 16:16:46
User entered 'No (N)'	System	05 Sep 2020 16:16:46

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:39', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bcd83f03-adb5-49ac-90db-b4d4d581e68d'	System	05 Sep 2020 16:16:46
User entered 'No (N)'	System	05 Sep 2020 16:16:46

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:41', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bcd83f03-adb5-49ac-90db-b4d4d581e68d'	System	05 Sep 2020 16:16:46
User entered 'None (1)'	System	05 Sep 2020 16:16:46

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:45', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bcd83f03-adb5-49ac-90db-b4d4d581e68d' User entered '05 Sep 2020 12:16'	System	05 Sep 2020 16:16:46
	System	05 Sep 2020 16:16:46

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 6'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:13', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '356ce4f1-cc61-4bcc-85b1-f5ced3c04420'	System	06 Sep 2020 16:02:07
User entered 'None (1)'	System	06 Sep 2020 16:02:07

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:17', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '356ce4f1-cc61-4bcc-85b1-f5ced3c04420'	System	06 Sep 2020 16:02:07
User entered 'No (N)'	System	06 Sep 2020 16:02:07

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:19', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '356ce4f1-cc61-4bcc-85b1-f5ced3c04420'	System	06 Sep 2020 16:02:07
User entered 'No (N)'	System	06 Sep 2020 16:02:07

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:22', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '356ce4f1-cc61-4bcc-85b1-f5ced3c04420'	System	06 Sep 2020 16:02:07
User entered 'None (1)'	System	06 Sep 2020 16:02:07

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '356ce4f1-cc61-4bcc-85b1-f5ced3c04420'	System	06 Sep 2020 16:02:07
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 16:02:07

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 7'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:00:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1eb3cc28-f538-4488-8114-a8e2bf4ae0e3'	System	07 Sep 2020 16:01:39
User entered 'None (1)'	System	07 Sep 2020 16:01:39

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1eb3cc28-f538-4488-8114-a8e2bf4ae0e3'	System	07 Sep 2020 16:01:39
User entered 'No (N)'	System	07 Sep 2020 16:01:39

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:04', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1eb3cc28-f538-4488-8114-a8e2bf4ae0e3'	System	07 Sep 2020 16:01:39
User entered 'No (N)'	System	07 Sep 2020 16:01:39

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:07', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1eb3cc28-f538-4488-8114-a8e2bf4ae0e3'	System	07 Sep 2020 16:01:39
User entered 'None (1)'	System	07 Sep 2020 16:01:39

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:12', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1eb3cc28-f538-4488-8114-a8e2bf4ae0e3'	System	07 Sep 2020 16:01:39
User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:01:39

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edba7'	System	01 Sep 2020 19:57:48
User entered 'None (0)'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edba7'	System	01 Sep 2020 19:57:48
User entered 'None (0)'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edba7'	System	01 Sep 2020 19:57:48
User entered 'None (0)'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:32', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edba7f'	System	01 Sep 2020 19:57:48
User entered 'None (0)'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:35', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edba7'	System	01 Sep 2020 19:57:48
User entered 'None (0)'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:37', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edbaf7'	System	01 Sep 2020 19:57:48
User entered 'None (0)'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edba7'	System	01 Sep 2020 19:57:48
User entered 'No (N)'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T15:57:43', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'f68a0d97-c365-47a9-beb4-c463f3edba7'	System	01 Sep 2020 19:57:48
User entered '01 Sep 2020 15:57'	System	01 Sep 2020 19:57:48

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 15:46'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 18:16'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:07', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered 'None (0)'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:09', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered 'None (0)'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:12', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered 'None (0)'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered 'None (0)'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:19', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered 'None (0)'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:22', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered 'None (0)'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered 'No (N)'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-01T20:11:28', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2549e783-e778-46cd-aa7c-c4b7a0030c52'	System	02 Sep 2020 00:11:31
User entered '01 Sep 2020 20:11'	System	02 Sep 2020 00:11:31

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '01 Sep 2020 19:11'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 2'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:14', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered 'None (0)'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:17', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered 'None (0)'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered 'No interference with activity (1)'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:32', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered 'None (0)'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:35', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered 'None (0)'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:37', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered 'None (0)'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:40', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered 'No (N)'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-02T13:24:43', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '92b0e87c-da2a-40cb-9399-bb89ee055cf3'	System	02 Sep 2020 17:24:47
User entered '02 Sep 2020 13:24'	System	02 Sep 2020 17:24:47

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 3'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:07', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered 'None (0)'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:10', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered 'None (0)'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:13', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered 'None (0)'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:18', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered 'None (0)'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:20', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered 'None (0)'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:23', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered 'No (N)'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-03T12:32:26', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8a5eda79-9354-4a7d-9b08-fd5858b200db'	System	03 Sep 2020 16:32:29
User entered '03 Sep 2020 12:32'	System	03 Sep 2020 16:32:29

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 4'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:02:53', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered 'None (0)'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:03:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered 'None (0)'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:03:20', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered 'None (0)'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:03:22', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered 'None (0)'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:03:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered 'None (0)'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:03:27', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered 'None (0)'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:03:30', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered 'No (N)'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-04T12:03:34', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '958f27fc-51d5-49d6-8bfb-e748a5f12d9e'	System	04 Sep 2020 16:05:32
User entered '04 Sep 2020 12:03'	System	04 Sep 2020 16:05:32

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 5'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:50', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered 'None (0)'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered 'None (0)'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:54', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered 'None (0)'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:56', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered 'None (0)'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:16:58', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered 'None (0)'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:17:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered 'None (0)'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:17:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered 'No (N)'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-05T12:17:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9709ef3c-1e73-481b-8b7e-6e2bd57a0cd5'	System	05 Sep 2020 16:17:07
User entered '05 Sep 2020 12:17'	System	05 Sep 2020 16:17:07

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 6'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:31', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered 'None (0)'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:33', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered 'None (0)'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:36', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered 'None (0)'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:38', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered 'None (0)'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:41', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered 'None (0)'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:43', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered 'None (0)'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:46', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered 'No (N)'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-06T12:01:50', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '48dafb2b-7ab7-4757-8efa-96b3d4b25e50'	System	06 Sep 2020 16:02:42
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 16:02:42

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	01 Sep 2020 19:34:05
User entered 'Day 7'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:17', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered 'None (0)'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:19', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered 'None (0)'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:21', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered 'None (0)'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:23', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered 'None (0)'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered 'None (0)'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:28', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered 'None (0)'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:31', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered 'No (N)'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-09-07T12:01:35', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a3b232c9-72a3-4d79-a9a0-658f6d27c862'	System	07 Sep 2020 16:02:09
User entered '07 Sep 2020 12:01'	System	07 Sep 2020 16:02:09

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 19:34:05

US3182158

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 19:34:05

US3182158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:41:01

US3182158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered '8 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:41:01

US3182158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:41:01

US3182158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:41:01

US3182158

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:17:54
User entered 'Yes (Y)'	Alec Ireland (b) (4)	09 Sep 2020 17:41:05

US3182158

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	09 Sep 2020 17:41:05

US3182158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	17 Sep 2020 19:34:02

US3182158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '15 Sep 2020'	Alec Ireland (b) (4)	17 Sep 2020 19:34:02

US3182158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	17 Sep 2020 19:34:02

US3182158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	17 Sep 2020 19:34:02

US3182158

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	17 Sep 2020 19:34:06

US3182158

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	17 Sep 2020 19:34:06

US3182158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:43:59

US3182158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '22 Sep 2020'	Alec Ireland (b) (4)	24 Sep 2020 16:43:59

US3182158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	24 Sep 2020 16:43:59

US3182158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:43:59

US3182158

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:44:03

US3182158

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	24 Sep 2020 16:44:03

US3182158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	05 Oct 2020 17:00:36

US3182158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '29 Sep 2020'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:36

US3182158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[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 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:36

US3182158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'VISIT3'	System	05 Oct 2020 17:00:36

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '29 Sep 2020'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:44'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '29 Sep 2020 14:44'	System	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '98.7' F	(b) (4) Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '79'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'bpm'	System	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '15'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'breaths/min'	System	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '126'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '83'	Cassie Uminski (b) (4)	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'mmHg'	System	05 Oct 2020 17:00:58

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34

US3182158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34

US3182158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Oct 2020 17:01:04

US3182158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered empty.	Cassie Uminski (b) (4)	05 Oct 2020 17:01:04

US3182158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	05 Oct 2020 17:01:15

US3182158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '29 Sep 2020'	Cassie Uminski (b) (4)	05 Oct 2020 17:01:15

US3182158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered '14:55'	Cassie Uminski (b) (4)	05 Oct 2020 17:01:15

US3182158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered '29 Sep 2020 14:55'	System	05 Oct 2020 17:01:15

US3182158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:12:33
User entered 'Yes (Y)'	Cassie Uminski	05 Oct 2020 17:01:21

US3182158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	05 Oct 2020 17:01:21

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 64'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-07T15:16:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '22fe53ff-8f09-4dba-aada-ede39ddfca07'	System	07 Oct 2020 19:16:11
User entered 'No (N)'	System	07 Oct 2020 19:16:11

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-07T15:16:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '22fe53ff-8f09-4dba-aada-ede39ddfca07'	System	07 Oct 2020 19:16:11
User entered 'No (N)'	System	07 Oct 2020 19:16:11

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-07T15:16:09', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '22fe53ff-8f09-4dba-aada-edc39ddfca07'	System	07 Oct 2020 19:16:11
User entered '07 Oct 2020 15:16:09'	System	07 Oct 2020 19:16:11

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 71'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-11T09:44:26', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2a0331a1-bb5a-421e-a335-c504901b1459'	System	11 Oct 2020 13:44:37
User entered 'No (N)'	System	11 Oct 2020 13:44:37

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-11T09:44:29', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2a0331a1-bb5a-421e-a335-c504901b1459'	System	11 Oct 2020 13:44:37
User entered 'No (N)'	System	11 Oct 2020 13:44:37

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-11T09:44:36', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '2a0331a1-bb5a-421e-a335-c504901b1459'	System	11 Oct 2020 13:44:37
User entered '11 Oct 2020 09:44:36'	System	11 Oct 2020 13:44:37

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 78'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-18T11:47:54', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'becf2337-01ef-4462-b3ac-061e657882e2'	System	18 Oct 2020 15:48:04
User entered 'No (N)'	System	18 Oct 2020 15:48:04

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-18T11:47:58', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'becf2337-01ef-4462-b3ac-061e657882e2'	System	18 Oct 2020 15:48:04
User entered 'No (N)'	System	18 Oct 2020 15:48:04

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-10-18T11:48:02', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'becf2337-01ef-4462-b3ac-061e657882e2'	System	18 Oct 2020 15:48:04
User entered '18 Oct 2020 11:48:02'	System	18 Oct 2020 15:48:04

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 92'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-01T00:29:35', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd9c3126d-91c2-45a9-b8d3-9f601d57d5e8'	System	01 Nov 2020 04:29:44
User entered 'No (N)'	System	01 Nov 2020 04:29:44

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-01T00:29:38', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd9c3126d-91c2-45a9-b8d3-9f601d57d5e8'	System	01 Nov 2020 04:29:44
User entered 'No (N)'	System	01 Nov 2020 04:29:44

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-01T00:29:41', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd9c3126d-91c2-45a9-b8d3-9f601d57d5e8'	System	01 Nov 2020 04:29:44
User entered '01 Nov 2020 00:29:41'	System	01 Nov 2020 04:29:44

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 99'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-08T00:25:51', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9530570b-ed45-415c-86da-bda2b511c2f4'	System	08 Nov 2020 05:26:03
User entered 'No (N)'	System	08 Nov 2020 05:26:03

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-08T00:25:55', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9530570b-ed45-415c-86da-bda2b511c2f4'	System	08 Nov 2020 05:26:03
User entered 'No (N)'	System	08 Nov 2020 05:26:03

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-08T00:25:59', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9530570b-ed45-415c-86da-bda2b511c2f4'	System	08 Nov 2020 05:26:03
User entered '08 Nov 2020 00:25:59'	System	08 Nov 2020 05:26:03

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered 'Day 106'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-15T10:29:39', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '3bbe6286-2df0-485c-944e-04d786109a61'	System	15 Nov 2020 15:29:55
User entered 'No (N)'	System	15 Nov 2020 15:29:55

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-15T10:29:46', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '3bbe6286-2df0-485c-944e-04d786109a61'	System	15 Nov 2020 15:29:55
User entered 'No (N)'	System	15 Nov 2020 15:29:55

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-15T10:29:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '3bbe6286-2df0-485c-944e-04d786109a61'	System	15 Nov 2020 15:29:55
User entered '15 Nov 2020 10:29:52'	System	15 Nov 2020 15:29:55

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 19:26:18

US3182158

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:08:33
Data entry locked.	System	04 Aug 2020 19:26:18
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 19:26:18

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2020-11-22T08:42:06', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '559622fa-9e96-43a8-a09a-79a2e441f917'	System	22 Nov 2020 13:42:22
User entered 'No (N)'	System	22 Nov 2020 13:42:22

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2020-11-22T08:42:12', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '559622fa-9e96-43a8-a09a-79a2e441f917'	System	22 Nov 2020 13:42:22
User entered 'No (N)'	System	22 Nov 2020 13:42:22

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-22T08:42:21', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '559622fa-9e96-43a8-a09a-79a2e441f917'	System	22 Nov 2020 13:42:22
User entered '22 Nov 2020 08:42:21'	System	22 Nov 2020 13:42:22

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2020-11-27T18:01:01', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'ee505a58-66ad-44a2-aac6-ad1321db5c10'	System	27 Nov 2020 23:01:14
User entered 'No (N)'	System	27 Nov 2020 23:01:14

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2020-11-27T18:01:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'ee505a58-66ad-44a2-aac6-ad1321db5c10'	System	27 Nov 2020 23:01:14
User entered 'No (N)'	System	27 Nov 2020 23:01:14

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-11-27T18:01:08', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'ee505a58-66ad-44a2-aac6-ad1321db5c10' User entered '27 Nov 2020 18:01:08'	System	27 Nov 2020 23:01:14
	System	27 Nov 2020 23:01:14

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2020-12-03T08:54:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'cd663d10-2a5b-4c9e-bd9d-41bf6febada7'	System	03 Dec 2020 13:55:09
User entered 'No (N)'	System	03 Dec 2020 13:55:09

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2020-12-03T08:55:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'cd663d10-2a5b-4c9e-bd9d-41bf6febada7'	System	03 Dec 2020 13:55:09
User entered 'No (N)'	System	03 Dec 2020 13:55:09

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-12-03T08:55:05', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'cd663d10-2a5b-4c9e-bd9d-41bf6febada7'	System	03 Dec 2020 13:55:09
User entered '03 Dec 2020 08:55:05'	System	03 Dec 2020 13:55:09

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2020-12-10T08:14:44', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'b43ede1a-ed7f-4f67-9b04-47fafa6517b5'	System	10 Dec 2020 13:15:03
User entered 'No (N)'	System	10 Dec 2020 13:15:03

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2020-12-10T08:14:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'b43ede1a-ed7f-4f67-9b04-47fafa6517b5'	System	10 Dec 2020 13:15:03
User entered 'No (N)'	System	10 Dec 2020 13:15:03

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-12-10T08:14:55', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'b43ede1a-ed7f-4f67-9b04-47fafa6517b5' User entered '10 Dec 2020 08:14:55'	System	10 Dec 2020 13:15:03
	System	10 Dec 2020 13:15:03

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2020-12-17T06:31:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8155e9be-10e9-4d80-8469-8a4c20f1bc5c'	System	17 Dec 2020 11:32:04
User entered 'No (N)'	System	17 Dec 2020 11:32:04

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2020-12-17T06:31:55', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8155e9be-10e9-4d80-8469-8a4c20f1bc5c'	System	17 Dec 2020 11:32:04
User entered 'No (N)'	System	17 Dec 2020 11:32:04

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-12-17T06:32:01', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8155e9be-10e9-4d80-8469-8a4c20f1bc5c'	System	17 Dec 2020 11:32:04
User entered '17 Dec 2020 06:32:01'	System	17 Dec 2020 11:32:04

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2020-12-24T07:36:44', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9a9015cc-ba58-41fb-9342-19b6881bdd93'	System	24 Dec 2020 12:36:57
User entered 'No (N)'	System	24 Dec 2020 12:36:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2020-12-24T07:36:47', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9a9015cc-ba58-41fb-9342-19b6881bdd93'	System	24 Dec 2020 12:36:57
User entered 'No (N)'	System	24 Dec 2020 12:36:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-12-24T07:36:52', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '9a9015cc-ba58-41fb-9342-19b6881bdd93'	System	24 Dec 2020 12:36:57
User entered '24 Dec 2020 07:36:52'	System	24 Dec 2020 12:36:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2020-12-31T08:37:17', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '79b3fb71-c780-481a-8586-1a521947841d'	System	31 Dec 2020 13:37:30
User entered 'No (N)'	System	31 Dec 2020 13:37:30

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2020-12-31T08:37:19', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '79b3fb71-c780-481a-8586-1a521947841d'	System	31 Dec 2020 13:37:30
User entered 'No (N)'	System	31 Dec 2020 13:37:30

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2020-12-31T08:37:25', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '79b3fb71-c780-481a-8586-1a521947841d'	System	31 Dec 2020 13:37:30
User entered '31 Dec 2020 08:37:25'	System	31 Dec 2020 13:37:30

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-01-07T08:29:59', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a4b3474d-9351-45c7-b110-be5550eed2c8'	System	07 Jan 2021 13:30:09
User entered 'No (N)'	System	07 Jan 2021 13:30:09

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-01-07T08:30:01', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a4b3474d-9351-45c7-b110-be5550eed2c8'	System	07 Jan 2021 13:30:09
User entered 'No (N)'	System	07 Jan 2021 13:30:09

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-01-07T08:30:04', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'a4b3474d-9351-45c7-b110-be5550eed2c8'	System	07 Jan 2021 13:30:09
User entered '07 Jan 2021 08:30:04'	System	07 Jan 2021 13:30:09

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-01-18T15:59:43', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '5fed6521-89e4-484b-9838-d9e7b8f039f0'	System	18 Jan 2021 20:59:51
User entered 'No (N)'	System	18 Jan 2021 20:59:51

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-01-18T15:59:45', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '5fed6521-89e4-484b-9838-d9e7b8f039f0'	System	18 Jan 2021 20:59:51
User entered 'No (N)'	System	18 Jan 2021 20:59:51

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-01-18T15:59:48', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '5fed6521-89e4-484b-9838-d9e7b8f039f0'	System	18 Jan 2021 20:59:51
User entered '18 Jan 2021 15:59:48'	System	18 Jan 2021 20:59:51

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-01-21T07:00:43', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bbd1703b-5447-4742-a03f-a37f61a9b113'	System	21 Jan 2021 12:00:52
User entered 'No (N)'	System	21 Jan 2021 12:00:52

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-01-21T07:00:45', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bbd1703b-5447-4742-a03f-a37f61a9b113'	System	21 Jan 2021 12:00:52
User entered 'No (N)'	System	21 Jan 2021 12:00:52

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-01-21T07:00:49', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bbd1703b-5447-4742-a03f-a37f61a9b113' User entered '21 Jan 2021 07:00:49'	System	21 Jan 2021 12:00:52
	System	21 Jan 2021 12:00:52

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-01-28T07:37:12', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f98e4f1-2011-4137-8750-ae532460540d'	System	28 Jan 2021 12:37:24
User entered 'No (N)'	System	28 Jan 2021 12:37:24

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-01-28T07:37:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f98e4f1-2011-4137-8750-ae532460540d'	System	28 Jan 2021 12:37:24
User entered 'No (N)'	System	28 Jan 2021 12:37:24

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-01-28T07:37:20', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '8f98e4f1-2011-4137-8750-ae532460540d' User entered '28 Jan 2021 07:37:20'	System	28 Jan 2021 12:37:24
	System	28 Jan 2021 12:37:24

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-02-04T11:16:58', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0ccee77-21e3-49b2-84fe-927f621abfa0'	System	04 Feb 2021 16:17:10
User entered 'No (N)'	System	04 Feb 2021 16:17:10

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-02-04T11:17:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0ccee77-21e3-49b2-84fe-927f621abfa0'	System	04 Feb 2021 16:17:10
User entered 'No (N)'	System	04 Feb 2021 16:17:10

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-02-04T11:17:04', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '0ccee77-21e3-49b2-84fe-927f621abfa0'	System	04 Feb 2021 16:17:10
User entered '04 Feb 2021 11:17:04'	System	04 Feb 2021 16:17:10

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-02-15T17:49:55', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '190073f4-251e-474f-80f2-6a3f99bf4bd6'	System	15 Feb 2021 22:50:07
User entered 'No (N)'	System	15 Feb 2021 22:50:07

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-02-15T17:49:57', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '190073f4-251e-474f-80f2-6a3f99bf4bd6'	System	15 Feb 2021 22:50:07
User entered 'No (N)'	System	15 Feb 2021 22:50:07

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-02-15T17:50:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '190073f4-251e-474f-80f2-6a3f99bf4bd6'	System	15 Feb 2021 22:50:07
User entered '15 Feb 2021 17:50:00'	System	15 Feb 2021 22:50:07

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-02-18T06:55:16', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '332cf4ff-007f-4363-a014-3ff6fa72b17d'	System	18 Feb 2021 11:55:26
User entered 'No (N)'	System	18 Feb 2021 11:55:26

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-02-18T06:55:18', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '332cf4ff-007f-4363-a014-3ff6fa72b17d'	System	18 Feb 2021 11:55:26
User entered 'No (N)'	System	18 Feb 2021 11:55:26

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-02-18T06:55:21', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '332cf4ff-007f-4363-a014-3ff6fa72b17d' User entered '18 Feb 2021 06:55:21'	System	18 Feb 2021 11:55:26
	System	18 Feb 2021 11:55:26

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-02-26T11:49:50-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '6e92b213-baed-42a4-b580-3bb1f85d0b4d'	System	26 Feb 2021 16:49:59
User entered 'No (N)'	System	26 Feb 2021 16:49:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-02-26T11:49:52-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '6e92b213-baed-42a4-b580-3bb1f85d0b4d'	System	26 Feb 2021 16:49:59
User entered 'No (N)'	System	26 Feb 2021 16:49:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-02-26T11:49:54-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '6e92b213-baed-42a4-b580-3bb1f85d0b4d' User entered '26 Feb 2021 11:49:54'	System	26 Feb 2021 16:49:59
	System	26 Feb 2021 16:49:59

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-03-04T07:37:36-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd88ecf59-90c9-4334-97ed-32f40d24674e'	System	04 Mar 2021 12:37:46
User entered 'No (N)'	System	04 Mar 2021 12:37:46

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-03-04T07:37:38-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd88ecf59-90c9-4334-97ed-32f40d24674e'	System	04 Mar 2021 12:37:46
User entered 'No (N)'	System	04 Mar 2021 12:37:46

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-03-04T07:37:42-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd88ecf59-90c9-4334-97ed-32f40d24674e' User entered '04 Mar 2021 07:37:42'	System	04 Mar 2021 12:37:46
	System	04 Mar 2021 12:37:46

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-03-13T12:31:34-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '26d85d04-1767-4940-8de6-ef55c3856a41'	System	13 Mar 2021 17:31:48
User entered 'No (N)'	System	13 Mar 2021 17:31:48

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-03-13T12:31:38-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '26d85d04-1767-4940-8de6-ef55c3856a41'	System	13 Mar 2021 17:31:48
User entered 'No (N)'	System	13 Mar 2021 17:31:48

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-03-13T12:31:45-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '26d85d04-1767-4940-8de6-ef55c3856a41'	System	13 Mar 2021 17:31:48
User entered '13 Mar 2021 12:31:45'	System	13 Mar 2021 17:31:48

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-03-18T07:45:00-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1c4cd572-79ca-47e7-b134-9006d856f6f1'	System	18 Mar 2021 11:45:14
User entered 'No (N)'	System	18 Mar 2021 11:45:14

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-03-18T07:45:08-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1c4cd572-79ca-47e7-b134-9006d856f6f1'	System	18 Mar 2021 11:45:14
User entered 'No (N)'	System	18 Mar 2021 11:45:14

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-03-18T07:45:12-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1c4cd572-79ca-47e7-b134-9006d856f6f1' User entered '18 Mar 2021 07:45:12'	System	18 Mar 2021 11:45:14
	System	18 Mar 2021 11:45:14

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-03-26T07:50:09-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd5483ce2-e030-4c15-88f3-a39d2f229a5b'	System	26 Mar 2021 11:50:20
User entered 'No (N)'	System	26 Mar 2021 11:50:20

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-03-26T07:50:11-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd5483ce2-e030-4c15-88f3-a39d2f229a5b'	System	26 Mar 2021 11:50:20
User entered 'No (N)'	System	26 Mar 2021 11:50:20

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-03-26T07:50:14-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd5483ce2-e030-4c15-88f3-a39d2f229a5b' User entered '26 Mar 2021 07:50:14'	System	26 Mar 2021 11:50:20
	System	26 Mar 2021 11:50:20

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-04-02T10:17:32-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1c8ae6bf-1985-44c3-aeef-e03c3d633815'	System	02 Apr 2021 14:17:44
User entered 'No (N)'	System	02 Apr 2021 14:17:44

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-04-02T10:17:34-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1c8ae6bf-1985-44c3-aeef-e03c3d633815'	System	02 Apr 2021 14:17:44
User entered 'No (N)'	System	02 Apr 2021 14:17:44

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-04-02T10:17:41-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '1c8ae6bf-1985-44c3-aeef-e03c3d633815'	System	02 Apr 2021 14:17:44
User entered '02 Apr 2021 10:17:41'	System	02 Apr 2021 14:17:44

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-04-08T07:44:42-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '320942d7-73ee-4320-a6ad-0c316cbb4450'	System	08 Apr 2021 11:44:51
User entered 'No (N)'	System	08 Apr 2021 11:44:51

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-04-08T07:44:44-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '320942d7-73ee-4320-a6ad-0c316cbb4450'	System	08 Apr 2021 11:44:51
User entered 'No (N)'	System	08 Apr 2021 11:44:51

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-04-08T07:44:48-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '320942d7-73ee-4320-a6ad-0c316cbb4450'	System	08 Apr 2021 11:44:51
User entered '08 Apr 2021 07:44:48'	System	08 Apr 2021 11:44:51

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-04-19T13:48:31-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd0b73d2a-4771-489d-bb8c-91bd1c7e6244'	System	19 Apr 2021 17:48:40
User entered 'No (N)'	System	19 Apr 2021 17:48:40

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-04-19T13:48:33-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd0b73d2a-4771-489d-bb8c-91bd1c7e6244'	System	19 Apr 2021 17:48:40
User entered 'No (N)'	System	19 Apr 2021 17:48:40

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-04-19T13:48:36-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'd0b73d2a-4771-489d-bb8c-91bd1c7e6244'	System	19 Apr 2021 17:48:40
User entered '19 Apr 2021 13:48:36'	System	19 Apr 2021 17:48:40

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[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 (790c735317fcabe7)', Time: '2021-04-22T07:26:21-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bef07d38-0695-47ac-abd8-11cfd114111'	System	22 Apr 2021 11:26:35
User entered 'No (N)'	System	22 Apr 2021 11:26:35

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

Have you been exposed to someone with 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 (790c735317fcabe7)', Time: '2021-04-22T07:26:24-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bef07d38-0695-47ac-abd8-11cfd114111'	System	22 Apr 2021 11:26:35
User entered 'No (N)'	System	22 Apr 2021 11:26:35

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-04-22T07:26:27-04:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: 'bef07d38-0695-47ac-abd8-11cfcd114111'	System	22 Apr 2021 11:26:35
User entered '22 Apr 2021 07:26:27'	System	22 Apr 2021 11:26:35

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:46:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:46:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:46:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:46:57

US3182158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:46:57
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:46:57

US3182158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:33:21

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)	26 Apr 2021 03:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-03-02T12:08:23-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '3aa28620-b4b7-4d57-ab2a-bdd74aff2d01'	System	02 Mar 2021 17:15:58
User entered 'No (N)'	System	02 Mar 2021 17:15:58

US3182158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:33:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:57:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (790c735317fcabe7)', Time: '2021-03-02T12:08:28-05:00', User OID: 'PatientReportedOutcome (US3182158)', ODM File OID: '3aa28620-b4b7-4d57-ab2a-bdd74aff2d01' User entered '02 Mar 2021 12:08:28'	System	02 Mar 2021 17:15:58
	System	02 Mar 2021 17:15:58

US3182158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski	06 Nov 2020 15:23:54

US3182158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '29 Oct 2020'	Cassie Uminski	06 Nov 2020 15:23:54

US3182158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	06 Nov 2020 15:23:54

US3182158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	06 Nov 2020 15:23:54
	(b) (4)	

US3182158

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	06 Nov 2020 15:24:07

US3182158

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:00:34
User entered 'I'	System	06 Nov 2020 15:24:07

US3182158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Gabby Jacobs (b) (4)	21 Dec 2020 20:05:42

US3182158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '01 Dec 2020'	Gabby Jacobs (b) (4)	21 Dec 2020 20:05:42

US3182158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	21 Dec 2020 20:05:42

US3182158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered empty.	(b) (4) Gabby Jacobs (b) (4) (b) (4)	21 Dec 2020 20:05:42

US3182158

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	21 Dec 2020 20:04:21

US3182158

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered 'I'	System	21 Dec 2020 20:04:21

US3182158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 06:43:17
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	17 Feb 2021 17:51:59
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:35:38
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:04:25

US3182158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 09:30:13
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	17 Feb 2021 17:51:56
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:11:15
User entered '28 Dec 2020'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:04:25

US3182158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:04:25

US3182158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered empty.	(b) (4) Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:04:25

US3182158

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 15:04:34

US3182158

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered 'I'	System	05 Jan 2021 15:04:34

US3182158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 14:15:06

US3182158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '27 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 14:15:06

US3182158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	28 Jan 2021 14:15:06

US3182158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	28 Jan 2021 14:15:06
	(b) (4)	

US3182158

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 14:15:22

US3182158

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered 'I'	System	28 Jan 2021 14:15:22

US3182158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Feb 2021 17:51:18

US3182158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User closed query 'Per GCL Lab Recon: Immuno : Sample dated "16` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).		12 Mar 2021 09:34:15
Query 'Per GCL Lab Recon: Immuno : Sample dated "16` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	11 Mar 2021 18:46:05
User opened query 'Per GCL Lab Recon: Immuno : Sample dated "16` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:01:23
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:23:48
User entered '16 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	17 Feb 2021 17:51:18

US3182158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[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 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	17 Feb 2021 17:51:18

US3182158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered 'VISIT4'	System	17 Feb 2021 17:51:18

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered 'No (N)'	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered empty.	System	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	(b) (4)	31 Mar 2021 14:14:10
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	(b) (4)	31 Mar 2021 14:14:10
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered empty.	System	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered empty.	System	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered empty.	System	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:55
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered empty.	System	31 Mar 2021 14:14:10

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30

US3182158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30

US3182158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Feb 2021 17:51:29

US3182158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered empty.	Cassie Uminski (b) (4)	17 Feb 2021 17:51:29

US3182158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Mar 2021 18:45:54

US3182158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '16 Feb 2021'	Cassie Uminski (b) (4)	11 Mar 2021 18:45:54

US3182158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '14:24'	Cassie Uminski (b) (4)	11 Mar 2021 18:45:54

US3182158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered '16 Feb 2021 14:24'	System	11 Mar 2021 18:45:54

US3182158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Feb 2021 17:51:33

US3182158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:30
User entered 'I'	System	17 Feb 2021 17:51:33

US3182158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:37
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:52
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 14:44:13

US3182158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:37
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:52
User entered '30 Mar 2021'	Cassie Uminski (b) (4)	07 Apr 2021 14:44:13

US3182158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:37
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 14:44:13

US3182158

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:37
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:52
User entered empty.	(b) (4)	07 Apr 2021 14:44:13
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:37
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:46:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 14:44:16

US3182158

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:37
User entered 'I'	System	07 Apr 2021 14:44:16

US3182158

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:07

US3182158

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '26 Jan 2021'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:07

US3182158

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[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 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:07

US3182158

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User entered 'UNBLND_DECIDE'	System	17 Feb 2021 17:48:07

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '26 Jan 2021'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[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 22:59:04
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:16:14

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:16:14

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '26 Jan 2021'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'mRNA-1273 (mRNA-1273)'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'mRNA-1273 (mRNA-1273)'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'mRNA-1273 (mRNA-1273)'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User entered empty.	System	17 Feb 2021 17:48:29

US3182158

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User entered empty.	System	17 Feb 2021 17:48:29

US3182158

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Feb 2021 17:50:34

US3182158

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '26 Jan 2021'	Cassie Uminski (b) (4)	17 Feb 2021 17:50:34

US3182158

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '11:07'	Cassie Uminski (b) (4)	17 Feb 2021 17:50:34

US3182158

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User entered '26 Jan 2021 11:07'	System	17 Feb 2021 17:50:34

US3182158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Feb 2021 17:49:00

US3182158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '26 Jan 2021'	Cassie Uminski (b) (4)	17 Feb 2021 17:49:00

US3182158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered '10:48'	Cassie Uminski (b) (4)	17 Feb 2021 17:49:00

US3182158

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:04
User entered '26 Jan 2021 10:48'	System	17 Feb 2021 17:49:00

US3182158

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:33:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:49
DataPoint Verified.		22 Apr 2021 12:22:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 20:52:24
User entered 'Yes (Y)' reason for change: Data Entry Error	System	26 Jan 2021 20:52:24
User opened query 'Data is required. Please complete.' (Site from System).	Cassie Uminski (b) (4)	26 Jan 2021 20:52:24
User entered empty.	(b) (4)	
	System	26 Jan 2021 20:52:20
	Cassie Uminski (b) (4)	26 Jan 2021 20:52:20
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:37
Reviewed for Safety.		27 Jan 2021 18:11:30
User entered 'USA-US075-2021-mRNA-1273-P301000004'	System	27 Jan 2021 18:11:22
User entered 'New'	(b) (4), (b) (6)	27 Jan 2021 18:11:22

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 20:58:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 20:58:50
Data point term sent to Coder	System	26 Jan 2021 20:57:33
User entered 'Herniated disc'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:41
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:43
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:45
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:33
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms in Sep 2020, please consider updating event start date to onset date of symptoms.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:39:10
User entered '12 Dec 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	23 Feb 2021 16:54:55
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms in Sep 2020, please consider updating event start date to onset date of symptoms.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 15:48:33
User entered '12 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:48
User entered empty.	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:50
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:53
User entered '13 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:59
User entered empty.	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:11
User closed query 'If they were hospitalized then this is grade 4 per completion guidelines. ' (Site from CRA).		03 Mar 2021 14:29:08
Query 'If they were hospitalized then this is grade 4 per completion guidelines. ' answered with 'confirmed and updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:37:34
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:36:26
User opened query 'If they were hospitalized then this is grade 4 per completion guidelines. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:23:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:29:14
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 14:30:05
User entered '0'	Cassie Uminski (b) (4)	26 Jan 2021 20:57:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:11
User entered '0'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:13
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).		02 Mar 2021 15:38:21
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 15:48:56
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:15
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).' canceled (Site from Safety).		02 Mar 2021 15:38:29
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)	04 Feb 2021 15:48:49
User entered '12 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:17
User entered '13 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 14:30:20
User entered 'No (N)'	Cassie Uminski (b) (4)	26 Jan 2021 20:57:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:21
User entered empty.	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:23
User entered '0'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:25
User entered '0'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:26
User entered '0'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:29
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:32
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:33
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:36
User entered '0'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	26 Jan 2021 20:57:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:52:04
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:19:33
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated conproc page' (Site from DM).	Jennifer Gaston (b) (4)	02 Mar 2021 16:47:07
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:34:08
User entered 'I'	Cassie Uminski (b) (4)	26 Jan 2021 20:57:31
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:52:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4)	26 Jan 2021 20:57:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:52:23
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	26 Jan 2021 20:57:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV requery: Please clarify as this still has not been addressed. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 16:12:33
User closed query 'PV requery: Please clarify as this still has not been addressed. 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).		08 Apr 2021 16:12:22
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
Query 'PV requery: Please clarify as this still has not been addressed. 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 'confirmed, per medical records, not done' (Site from Safety).	Jennifer Gaston (b) (4)	07 Apr 2021 16:01:14
	(b) (4)	
Signature has been broken.	Jennifer Gaston (b) (4)	07 Apr 2021 16:01:03
	(b) (4)	
User entered 'SUBJECT STARTED HAVING NECK PAIN IN SEPTEMBER 2020, SAW DOCTOR IN DECEMBER 2020. SCHEDULED HERNIATED DISC REPAIR IN JANUARY. SURGERY DATE WAS 1/12/2021 AND SUBJECT WAS HOSPITALIZED UNTIL 1/13/2021.	Jennifer Gaston (b) (4)	07 Apr 2021 16:01:03
	(b) (4)	
Per medical records, subject did not have a COVID-19 test prior to procedure.' reason for change: Data Entry Error		
Query 'PV requery: Please clarify as this still has not been addressed. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If unknown, please indicate so. ' answered with 'answer provided in previous query' (Site from Safety).	Jennifer Gaston (b) (4)	07 Apr 2021 15:55:52
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV requery: Please clarify as this still has not been addressed. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 12:10:04
User opened query 'PV requery: Please clarify as this still has not been addressed. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 12:09:50
User closed query 'Per DM CLR: Narrative = SUBJECT STARTED HAVING NECK PAIN IN SEPTEMBER 2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 10:56:28
User closed query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 16:56:35
User closed query 'PV requery: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		26 Mar 2021 16:56:29
User closed query 'PV requery: 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).		26 Mar 2021 16:56:23
User signature succeeded.		
	Mary Beth Manning (b) (4)	26 Mar 2021 13:18:49

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STARTED HAVING NECK PAIN IN SEPTEMBER 2020, SAW DOCTOR IN DECEMBER 2020. SCHEDULED HERNIATED DISC REPAIR IN JANUARY. SURGERY DATE WAS 1/12/2021 AND SUBJECT WAS HOSPITALIZED UNTIL 1/13/2021.' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 16:03:02
Query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4)	25 Mar 2021 13:32:43
Query 'Per DM CLR: Narrative = SUBJECT STARTED HAVING NECK PAIN IN SEPTEMBER 2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	Cassie Uminski (b) (4)	25 Mar 2021 13:11:14
' answered with 'This will be added as an AE' (Site from DM).		
Query 'PV requery: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4)	25 Mar 2021 13:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STARTED HAVING NECK PAIN IN SEPTEMBER 2020, SAW DOCTOR IN DECEMBER 2020. SCHEDULED HERNIATED DISC REPAIR IN JANUARY. SURGERY DATE WAS 1/12/2021 AND SUBJECT WAS HOSPITALIZED UNTIL 1/13/2021. COVID NASAL SWAB PERFORMED ON 1/16/2021, RESULTS NEGATIVE. Lab test performed: CBC: RBC=4.86, WBC=7.8, MCV=80, Neutrophils=58.3%) CMP (NA+=139, Cl-=104, BUN 9, Glucose=106, K+=3.6, HCo3-=21, Creatinine= 1.01, total bilirubin=0.4, AST=19, ALT=23, ALK=53, calcium=9.2, Anion Gap=18, Albumin=4.1, total protein=6.7) Coagulation panel: PT=10.7 INR= 0.9, PTT=24L) type and screen. Results of labs were within normal limits, units not given. Imaging included chest X-Ray, CT PE, CT scan of Neck. Chest X ray showed no acute cardiopulmonary process, CT PE showed no evidence of pulmonary embolism. CT scan of the neck did show concern for prevertebral fluid collection extending from C2-C5. This not appear to be infectious.' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:08:02
Query 'PV requery: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 12:51:34
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 12:51:21
User entered 'SUBJECT STARTED HAVING NECK PAIN IN SEPTEMBER 2020, SAW DOCTOR IN DECEMBER 2020. SCHEDULED HERNIATED DISC REPAIR IN JANUARY. SURGERY DATE WAS 1/12/2021 AND SUBJECT WAS HOSPITALIZED UNTIL 1/13/2021. COVID nasal swab performed on 1/16/2021, results negative.' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 12:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = SUBJECT STARTED HAVING NECK PAIN IN SEPTEMBER 2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:49:00
User opened query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 19:26:13
User opened query 'PV requery: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 19:25:58
User opened query 'PV requery: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 19:25:34
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User closed query 'Please add the disc repair to the concomitant procedures page. ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 14:25:41
User closed query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:16:21

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:16:18
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).		03 Mar 2021 16:15:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'As of 2/25/2021, medical records still pending.' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 17:12:31
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 'As of 2/25/2021, medical records still pending.' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 17:12:28
Query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated known conmeds at this time, if applicable, will update accordingly as records are received ' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:50:02
Query 'Please add the disc repair to the concomitant procedures page.' answered with 'updated conproc page' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:47:29

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Please add the disc repair to the concomitant procedures page. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:32:03
User opened query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		04 Feb 2021 15:48:42
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 15:48:25
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)	04 Feb 2021 15:48:19
User entered 'Subject started having neck pain in September 2020, saw Doctor in December 2020. Scheduled herniated disc repair in January. Surgery Date was 1/12/2021 and subject was hospitalized until 1/13/2021. Medical records requested.'	Cassie Uminski (b) (4) (b) (4)	26 Jan 2021 20:57:31

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 20:57:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 20:57:31

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
User closed query 'Per DM CLR: Please confirm the AE term "EXACERBATION OF NECK SECONDARY TO PINCHED NERVE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).		14 Apr 2021 01:57:25
Query 'Per DM CLR: Please confirm the AE term "EXACERBATION OF NECK SECONDARY TO PINCHED NERVE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' answered with 'Medical hx updated to reflect ' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 16:03:21
User opened query 'Per DM CLR: Please confirm the AE term "EXACERBATION OF NECK SECONDARY TO PINCHED NERVE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:22:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:53:06
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:18:49
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:20:42

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) System	26 Mar 2021 10:20:42 25 Mar 2021 13:22:19
User entered 'Exacerbation of neck Secondary to pinched nerve'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:16
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '09 Sep 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:25
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
User entered empty.	System	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:27
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:28
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '12 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:32
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
User entered empty.	System	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:34
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:36
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:46
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:54
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:53:58
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:54:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:54:01
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:54:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
User closed query 'Source states NA. This must be related or not related. Please update as appropriate. ' (Site from CRA).	(b) (4)	14 Apr 2021 16:25:27
Query 'Source states NA. This must be related or not related. Please update as appropriate. ' answered with 'Corrected' (Site from CRA).	Naqib Ahmad (b) (4)	13 Apr 2021 19:59:04
User opened query 'Source states NA. This must be related or not related. Please update as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:47:36
User closed query 'This must be related or not related. Please update. ' (Site from CRA).	(b) (4)	11 Apr 2021 20:08:29
User signature succeeded.	Mary Beth Manning	09 Apr 2021 15:31:21
Query 'This must be related or not related. Please update. ' answered with 'corrected' (Site from CRA).	(b) (4)	09 Apr 2021 13:05:42
Signature has been broken.	Naqib Ahmad (b) (4)	09 Apr 2021 13:05:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 13:05:34
User opened query 'This must be related or not related. Please update. ' (Site from CRA).	Naqib Ahmad (b) (4)	09 Apr 2021 13:05:34
User closed query 'Source states NA but must be related or not related as it is after both doses of IP. Please update as appropriate. ' (Site from CRA).	(b) (4)	09 Apr 2021 02:25:22
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 02:25:22
Query 'Source states NA but must be related or not related as it is after both doses of IP. Please update as appropriate. ' answered with 'updated' (Site from CRA).	Mary Beth Manning	08 Apr 2021 00:08:25
Signature has been broken.	(b) (4)	07 Apr 2021 16:04:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	07 Apr 2021 16:04:39
DataPoint Un-verified.	(b) (4)	07 Apr 2021 16:04:39
	(b) (4), (b) (6)	31 Mar 2021 17:56:19
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Source states NA but must be related or not related as it is after both doses of IP. Please update as appropriate. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:56:16
		31 Mar 2021 17:54:31
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:54:33
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		13 Apr 2021 15:49:27
User closed query 'Source states none but should be NA since it is after both doses of IP. Please update a appropriate. ' (Site from CRA).		13 Apr 2021 15:49:25
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
Query 'Source states none but should be NA since it is after both doses of IP. Please update as appropriate. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4)	07 Apr 2021 16:05:34
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	07 Apr 2021 16:04:52
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	07 Apr 2021 16:03:44
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	07 Apr 2021 16:03:44
	(b) (4)	
User opened query 'Source states none but should be NA since it is after both doses of IP. Please update as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 17:56:55
DataPoint Un-verified.		31 Mar 2021 17:55:17
DataPoint Verified.		31 Mar 2021 17:54:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:57:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:57:14
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'l'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:57:17
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'I'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:57:19
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:57:21
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:21:37
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
DataPoint Verified.		31 Mar 2021 17:57:24
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
User entered '0'	System	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23
User entered 'I'	System	25 Mar 2021 13:21:37

US3182158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:45:23

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:57:49
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered	System	26 Mar 2021 17:06:50
'USA-US075-2021-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	26 Mar 2021 17:06:50

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:13:03
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' answered with 'correct as is per inv' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 16:34:10
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:33:04
DataPoint Verified.		31 Mar 2021 17:57:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Difficulty breathing - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 16:02:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:02:29
Data point term sent to Coder	System	25 Mar 2021 16:01:57
User entered 'Difficulty breathing'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 16:01:40

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:01
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '15 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:11
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:01:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '18 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:58:16
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:01:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 20:07:32
User closed query 'Please clarify if this should be grade 4 as they were hospitalized. Update CRF and source as appropriate. ' (Site from CRA).		11 Apr 2021 20:07:20
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
Query 'Please clarify if this should be grade 4 as they were hospitalized. Update CRF and source as appropriate. ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4)	07 Apr 2021 16:08:17
	(b) (4)	
Signature has been broken.	Jennifer Gaston (b) (4)	07 Apr 2021 16:08:09
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change:	Jennifer Gaston (b) (4)	07 Apr 2021 16:08:09
Data Entry Error	(b) (4)	
User opened query 'Please clarify if this should be grade 4 as they were hospitalized. Update CRF and source as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 18:00:59
User signature succeeded.		
	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:01
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:06
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:11
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'I'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:15
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '18 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:17
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:19
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:25
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:27
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:32
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:34
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:35
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:42
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	14 Apr 2021 01:57:42
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'entry error' (Site from DM). DataPoint Un-verified.	Mary Beth Manning (b) (4)	08 Apr 2021 00:08:25
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 16:08:50
User entered '0' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 16:08:41
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). DataPoint Verified.	Jennifer Gaston (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 16:08:41
User signature succeeded.	(b) (4), (b) (6) (b) (4)	03 Apr 2021 05:22:48
User entered '1'	Mary Beth Manning (b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 18:01:44
		26 Mar 2021 13:18:49
		25 Mar 2021 16:01:40

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:47
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'I'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:01:50
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = ON 1/15/2021 HE BEGAN INCREASING DYSPHASIA, DIFFICULTY SWALLOWING LIQUIDS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 01:57:45
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:13:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		08 Apr 2021 17:13:24
Query 'Per DM CLR: Narrative = ON 1/15/2021 HE BEGAN INCREASING DYSPHASIA, DIFFICULTY SWALLOWING LIQUIDS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'updated and AE added' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 16:29:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'conmed eCRF updated' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 16:14:25

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'done and sent today 4/7/2021' (Site from Safety).	Jennifer Gaston (b) (4)	07 Apr 2021 16:13:35
User opened query 'Per DM CLR: Narrative = ON 1/15/2021 HE BEGAN INCREASING DYSPHASIA, DIFFICULTY SWALLOWING LIQUIDS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:22:42
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:32:55
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 22:32:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:02:27
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:18:49

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED TO ER ON 1/16/2021 WITH COMPLAINTS OF DIFFICULTY BREATHING/SWALLOWING. PATIENT HAD A C4 TO C6 ACDF ON 1/12/2021. SUBJECT REPORTED BEGINNING ON 1/15/2021 HE BEGAN INCREASING DYSPHASIA, DIFFICULTY SWALLOWING LIQUIDS AND DIFFICULTY BREATHING. HE DID DENY ANY SHORTNESS OF BREATH. COVID NASAL SWAB PERFORMED ON 1/16/2021, RESULTS NEGATIVE. LAB TEST PERFORMED: CBC: RBC=4.86, WBC=7.8, MCV=80, NEUTROPHILS=58.3%) CMP (NA+=139, CL-=104, BUN 9, GLUCOSE= 106, K+=3.6, HCO3-=21, CREATININE= 1.01, TOTAL BILIRUBIN=0.4, AST=19, ALT=23, ALK=53, CALCIUM=9.2, ANION GAP=18, ALBUMIN=4.1, TOTAL PROTEIN=6.7) COAGULATION PANEL: PT=10.7 INR= 0.9, PTT=24L) TYPE AND SCREEN. RESULTS OF LABS WERE WITHIN NORMAL LIMITS, UNITS NOT GIVEN. IMAGING INCLUDED CHEST X-RAY, CT PE, CT SCAN OF NECK. CHEST X RAY SHOWED NO ACUTE CARDIOPULMONARY PROCESS, CT PE SHOWED NO EVIDENCE OF PULMONARY EMBOLISM. CT SCAN OF THE NECK DID SHOW CONCERN FOR PREVERTEBRAL FLUID COLLECTION EXTENDING FROM C2-C5. THIS NOT APPEAR TO BE INFECTIOUS.' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 16:03:25
User entered 'Subject presented to ER on 1/16/2021 with complaints of difficulty breathing/swallowing. Patient had a C4 to C6 ACDF on 1/12/2021. Subject reported beginning on 1/15/2021 he began increasing dysphasia, difficulty swallowing liquids and difficulty breathing. He did deny any shortness of breath.'	Cassie Uminski (b) (4)	25 Mar 2021 16:01:40

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 16:01:40

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 16:01:40

US3182158

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 16:01:40

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 15:31:21
	(b) (4)	
User entered	(b) (4), (b) (6)	08 Apr 2021 17:18:14
'USA-US075-2021-mRNA-1273-P301000011'		

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Cortical dysfunction NEC, PT: Aphasia, LLT: Dysphasia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 16:42:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 16:42:34
	(b) (4)	
Data point term sent to Coder	System	07 Apr 2021 16:41:55
User entered 'Dysphasia'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '15 Jan 2021'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 16:41:39

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'No (N)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '18 Jan 2021'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 16:41:39

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 17:23:54
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	Jennifer Gaston (b) (4)	07 Apr 2021 16:45:39
User entered '1'	(b) (4)	
	System	07 Apr 2021 16:41:39
	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '16 Jan 2021' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	07 Apr 2021 16:45:33
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '18 Jan 2021' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	07 Apr 2021 16:45:33
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '1'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered '0'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Records not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 23:19:21
User closed query 'PV Query: Records not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		30 Apr 2021 14:16:01
Query 'PV Query: Records not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records resent- please advise ' (Site from Safety).	Jennifer Gaston (b) (4)	29 Apr 2021 19:08:35
User opened query 'PV Query: Records not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 15:16:10
User closed query 'PV Query: Records not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		27 Apr 2021 23:07:07
Query 'PV Query: Records not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Confirmed redacted and sent ' (Site from Safety).	Jennifer Gaston (b) (4)	26 Apr 2021 17:46:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Records not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 17:27:29
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:42:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'confirmed- sent 4/22/2021' (Site from Safety).	Jennifer Gaston (b) (4)	22 Apr 2021 17:00:17
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 23:32:14
User signature succeeded.	Mary Beth Manning (b) (4)	08 Apr 2021 00:08:25
User entered empty.	Jennifer Gaston (b) (4)	07 Apr 2021 16:41:39

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 16:41:39

US3182158

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:33:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 16:41:39

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:33:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:49
DataPoint Verified.		13 Apr 2021 15:33:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Aug 2020 16:27:21

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Aug 2020 16:32:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:32:23
Data point term sent to Coder	System	10 Aug 2020 16:30:54
User entered 'Albuterol'	Cassie Uminski (b) (4) (b) (4)	10 Aug 2020 16:30:07

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Asthma'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:36
	(b) (4)	
Signature has been broken.	Jennifer Gaston (b) (4)	08 Apr 2021 20:41:21
	(b) (4)	
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'l'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'puff (PUFF)'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:43:29
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	10 Aug 2020 16:30:07
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	10 Aug 2020 16:30:07

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	10 Aug 2020 16:30:07
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 16:30:07

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 16:30:07

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 16:30:07

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 16:35:12
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 16:35:12
Data point term sent to Coder	System	17 Aug 2020 16:34:20
User entered 'Rosuvastatin'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 16:33:28

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'High Cholesterol'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '40'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:03:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 16:33:28
User entered 'un UNK 2017'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:33:28
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 16:33:28

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:33:28

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 16:33:28

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 16:36:14
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 16:36:14
Data point term sent to Coder	System	17 Aug 2020 16:35:21
User entered 'Lamotrigine'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 16:34:22

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Bipolar Disorder'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '200'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:03:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 16:34:22
User entered 'un UNK 2007'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:22
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 16:34:22

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:34:22

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 16:34:22

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 09:33:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 09:33:21
Data point term sent to Coder	System	17 Aug 2020 16:35:23
User entered 'Topiramate'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 16:34:51

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Bipolar Disorder'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '50'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:03:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 16:34:51
User entered 'un UNK 2011'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:34:51
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:34:51

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:34:51

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 16:34:51

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: TAMSULOSIN HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 16:36:14
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 16:36:14
Data point term sent to Coder	System	17 Aug 2020 16:35:25
User entered 'Tamsulosin HCL'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 16:35:19

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Enlarged Prostate'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0.4'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:03:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 16:35:19
User entered 'un Jun 2019'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:19
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:35:19

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:35:19

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 16:35:19

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 16:37:14
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 16:37:14
Data point term sent to Coder	System	17 Aug 2020 16:36:26
User entered 'Ezetimibe'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 16:35:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'High Cholesterol'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '10'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:03:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 16:35:43
User entered 'un May 2020'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:35:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:35:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:35:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 16:35:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 16:37:13
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 16:37:13
Data point term sent to Coder	System	17 Aug 2020 16:36:26
User entered 'Vitamin D3'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 16:36:17

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '10000'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'IU (IU)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:03:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 16:36:17
User entered 'un May 2020'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:17
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:36:17

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:36:17

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 16:36:17

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 13:42:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:42:38
Data point term sent to Coder	System	13 Oct 2020 13:42:02
User closed query 'For coding purposes, term is not codable as entered. Please clarify the Con Med ZYME Q10. If correct spelling, please provide the active ingredient, generic/trade name and update the term with your response' (Site from System).	System	13 Oct 2020 13:41:16
Query 'For coding purposes, term is not codable as entered. Please clarify the Con Med ZYME Q10. If correct spelling, please provide the active ingredient, generic/trade name and update the term with your response' answered with 'Updated' (Site from System).	Cassie Uminski (b) (4) (b) (4)	13 Oct 2020 13:41:16
User entered 'COEnZYME Q10' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	13 Oct 2020 13:41:11
User opened query 'For coding purposes, term is not codable as entered. Please clarify the Con Med ZYME Q10. If correct spelling, please provide the active ingredient, generic/trade name and update the term with your response' (Site from System).	Coder Import (b) (4) (b) (4)	23 Aug 2020 14:50:33
Data point term sent to Coder	System	17 Aug 2020 16:37:29
User entered 'zyme Q10'	Cassie Uminski (b) (4) (b) (4)	17 Aug 2020 16:36:41

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '300'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 02:03:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 16:36:41
User entered 'un May 2019'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	17 Aug 2020 16:36:41
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:36:41

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 16:36:41

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 16:36:41

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
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: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:18:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:18:16
Data point term sent to Coder	System	13 Oct 2020 13:49:17
Data point term sent to Coder	System	13 Oct 2020 13:45:11
User entered 'Prednisone dose pack'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'No (N)'	(b) (4)	13 Oct 2020 13:44:13
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User closed query 'Please update medical history as appropriate. ' (Site from CRA).	(b) (4)	25 Mar 2021 19:23:30
Query 'Please update medical history as appropriate. ' answered with 'Adverse events updated ' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:23:33
User opened query 'Please update medical history as appropriate. ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 10:28:50
User closed query 'Please clarify indication as pinched nerve is not listed as medical history or an AE. ' (Site from CRA).	(b) (4)	12 Mar 2021 10:28:50
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
Query 'Please clarify indication as pinched nerve is not listed as medical history or an AE. ' answered with 'This was corrected, a late entry was submitted - subject has a history of pinched nerve in neck onset 2018.' (Site from CRA).	(b) (4) Naqib Ahmad (b) (4) (b) (4)	11 Mar 2021 18:29:18
User opened query 'Please clarify indication as pinched nerve is not listed as medical history or an AE. ' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 14:41:40
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4)	28 Dec 2020 03:45:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'Prednisone dose pack is listed under con med. ' (Site from DM).	Gabby Jacobs (b) (4) (b) (4)	22 Dec 2020 19:25:21
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 16:05:47
User entered 'Pain from PINCHED NERVE IN NECK' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	13 Oct 2020 13:48:41

PRODUCTION RELEASE (v12.003
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US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pinched nerve in neck'	Cassie Uminski (b) (4) (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '4'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'mg (mg)'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	13 Oct 2020 13:44:13
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	13 Oct 2020 13:44:13
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	13 Oct 2020 13:44:13
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '28 Sep 2020'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '0'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User closed query 'Pain may be ongoing, but this medication typically is not. Please clarify. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:16:17
Query 'Pain may be ongoing, but this medication typically is not. Please clarify. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:26:02
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:25:55
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:25:55
User opened query 'Pain may be ongoing, but this medication typically is not. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 10:30:07
User closed query 'Please clarify if this is still ongoing as a dose pack is not usually given for months. ' (Site from CRA).		12 Mar 2021 10:30:07
User signature succeeded.	Mary Beth Manning (b) (4)	11 Mar 2021 22:12:55
Query 'Please clarify if this is still ongoing as a dose pack is not usually given for months. ' answered with 'chronic issue - pain is still on-going. ' (Site from CRA).	Naqib Ahmad (b) (4) (b) (4)	11 Mar 2021 18:30:09
User opened query 'Please clarify if this is still ongoing as a dose pack is not usually given for months. ' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 14:40:53
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
Signature has been broken.	Cassie Uminski (b) (4)	25 Mar 2021 13:25:55
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 13:25:55
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'No (N)'	Cassie Uminski (b) (4)	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User entered '1'	System	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User entered '1'	System	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:38
User entered '804 (804)'	System	13 Oct 2020 13:44:13

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 19:18:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 19:18:41
Data point term sent to Coder	System	11 Nov 2020 19:18:03
User entered 'Influenza vaccine'	Cassie Uminski (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'I'	(b) (4)	11 Nov 2020 19:18:02
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'injection'	Cassie Uminski (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	11 Nov 2020 19:18:02
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	11 Nov 2020 19:18:02
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '05 Oct 2020'	Cassie Uminski (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '05 Oct 2020'	Cassie Uminski (b) (4)	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'No (N)'	(b) (4)	11 Nov 2020 19:18:02
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User entered empty.	System	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User entered empty.	System	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:40
User entered empty.	System	11 Nov 2020 19:18:02

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:45:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:45:31
User signature succeeded.	Mary Beth Manning (b) (4)	11 Mar 2021 22:12:55
Data point term sent to Coder	System	02 Mar 2021 16:49:52
User entered 'Prednisone'	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'No (N)'	(b) (4)	02 Mar 2021 16:49:25
	Jennifer Gaston (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Post Surgical Inflammation'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '25'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'mg (mg)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	02 Mar 2021 16:49:25
	Jennifer Gaston (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'once daily (QD)'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	02 Mar 2021 16:49:25
	Jennifer Gaston (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'Oral (ORAL)'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered empty.	(b) (4)	02 Mar 2021 16:49:25
	Jennifer Gaston (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '23 Jan 2021'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '0'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'No (N)'	(b) (4)	02 Mar 2021 16:49:25
	Jennifer Gaston (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered '25 Jan 2021'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:12:55
User entered 'No (N)'	Jennifer Gaston (b) (4)	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User entered '1'	System	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User entered '1'	System	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:45
User entered '804 (804)'	System	02 Mar 2021 16:49:25

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 10:34:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:34:43
Data point term sent to Coder	System	25 Mar 2021 13:42:38
User entered 'Nitroglycerin'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:42:06

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'Prophylaxis'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered '0.4'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'Sublingual'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 16:50:01
	(b) (4)	
User entered '18 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:06
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 13:42:06

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 13:42:06

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 13:42:06

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:51:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:51:36
Data point term sent to Coder	System	07 Apr 2021 15:50:17
Coding entries removed.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:49:35
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 13:43:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 13:43:26
Data point term sent to Coder	System	25 Mar 2021 13:42:38
User entered 'Acetaminophen'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:42:38
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User closed query 'Per DM CLR: Please specify the location or type of PAIN SECONDARY TO PROCEDURE. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).		14 Apr 2021 01:58:12
User signature succeeded.	Mary Beth Manning (b) (4)	08 Apr 2021 00:08:25
Query 'Per DM CLR: Please specify the location or type of PAIN SECONDARY TO PROCEDURE. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'updated' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:49:41
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:49:35
User entered 'PAIN SECONDARY TO anterior cervical discectomy' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:49:35
User opened query 'Per DM CLR: Please specify the location or type of PAIN SECONDARY TO PROCEDURE. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:21:46
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
User entered 'Pain secondary to procedure'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '325'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:42:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:42:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:42:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 16:50:12
User entered '18 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:38
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:42:38
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '25 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	25 Mar 2021 13:42:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User entered empty.	System	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User entered empty.	System	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:51
User entered empty.	System	25 Mar 2021 13:42:38

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 11:17:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:17:48
Data point term sent to Coder	System	25 Mar 2021 13:44:39
User entered 'Polyethylene Glycol'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Post procedure constipation prophylaxis'	Cassie Uminski (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '17'	(b) (4)	25 Mar 2021 13:43:43
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'g (g)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:43:43
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User closed query 'Please clarify as page 13 of the fax states once per day. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:03:19
Query 'Please clarify as page 13 of the fax states once per day. ' answered with 'updated ' (Site from CRA). Signature has been broken.	Jennifer Gaston (b) (4) (b) (4) Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:50:19 07 Apr 2021 15:50:12
User entered 'once daily (QD)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:50:12
User opened query 'Please clarify as page 13 of the fax states once per day. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:11:49
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:43:43
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:43:43
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 16:50:33
User entered '18 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:43:43
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	25 Mar 2021 13:43:43
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '25 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	25 Mar 2021 13:43:43
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User entered '1'	System	07 Apr 2021 15:50:12
User entered empty.	System	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User entered '1'	System	07 Apr 2021 15:50:12
User entered empty.	System	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:51:53
User entered '804 (804)'	System	07 Apr 2021 15:50:12
User entered empty.	System	25 Mar 2021 13:43:43

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 08:47:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 08:47:20
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
Data point term sent to Coder	System	25 Mar 2021 13:45:40
User entered 'Zofran'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Post procedure nausea prophylaxis'	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '4'	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:44:48
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:44:48
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:44:48
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 16:50:57
User entered '18 Jan 2021'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '25 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:44:48
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User entered empty.	System	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User entered empty.	System	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:00
User entered empty.	System	25 Mar 2021 13:44:48

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:59:44
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 09:59:44
Data point term sent to Coder Coding entries removed.	System Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:52:20 07 Apr 2021 15:51:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:52:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:52:07
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
Data point term sent to Coder	System	25 Mar 2021 13:45:40
User entered 'Oxycodone'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	25 Mar 2021 13:45:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User closed query 'Per DM CLR: Please specify the location or type of PAIN SECONDARY TO PROCEDURE. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).		14 Apr 2021 01:58:39
User signature succeeded.	Mary Beth Manning (b) (4)	08 Apr 2021 00:08:25
Query 'Per DM CLR: Please specify the location or type of PAIN SECONDARY TO PROCEDURE. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'updated' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:52:00
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:51:55
User entered 'PAIN SECONDARY TO anterior cervical discectomy' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:51:55
User opened query 'Per DM CLR: Please specify the location or type of PAIN SECONDARY TO PROCEDURE. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:22:11
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
User entered 'Pain secondary to procedure'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		14 Apr 2021 01:58:44
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dosage confirmed per medical records' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:53:15
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:22:24
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
User entered '5'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:45:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:45:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 13:45:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 16:53:27
User entered '18 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:45:18
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:45:18
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 16:53:33
User entered '25 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:45:18
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	25 Mar 2021 13:45:18
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User entered empty.	System	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User entered empty.	System	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:05
User entered empty.	System	25 Mar 2021 13:45:18

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 16:55:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 16:55:28
Data point term sent to Coder	System	25 Mar 2021 16:55:14
User entered 'Docusate sodium'	Cassie Uminski (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Constipation prophylaxis'	Cassie Uminski (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User closed query 'Please clarify as page 6 and 13 of the fax have 100 mg but CRF has 50. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:06:37
Query 'Please clarify as page 6 and 13 of the fax have 100 mg but CRF has 50. ' answered with 'entry error, updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:54:21
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:54:12
User entered '100' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:54:12
User opened query 'Please clarify as page 6 and 13 of the fax have 100 mg but CRF has 50. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:49:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '50'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'mg (mg)'	Cassie Uminski (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 16:54:31
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	08 Apr 2021 00:08:25
User closed query 'Please clarify as pages 6 and 13 have 2 times a day but CRF has once daily. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:06:52
Query 'Please clarify as pages 6 and 13 have 2 times a day but CRF has once daily. ' answered with 'entry error, updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:55:22
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:55:01
User entered 'twice daily (BID)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 15:55:01
User opened query 'Please clarify as pages 6 and 13 have 2 times a day but CRF has once daily. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:49:49
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:33
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 16:54:31
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered empty.	(b) (4)	25 Mar 2021 16:54:31
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '13 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 16:54:31
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered '25 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:33
User entered 'No (N)'	(b) (4)	25 Mar 2021 16:54:31
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User entered '2'	System	07 Apr 2021 15:55:01
User entered '1'	System	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User entered '1'	System	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:33:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:52:08
User entered '804 (804)'	System	25 Mar 2021 16:54:31

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:33:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:30:51
User closed query 'Should this be yes since they had surgery to repair the herniated disc? ' (Site from CRA).		03 Mar 2021 14:30:49
Query 'Should this be yes since they had surgery to repair the herniated disc? ' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:45:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:45:48
User opened query 'Should this be yes since they had surgery to repair the herniated disc? ' (Site from CRA).	(b) (4), (b) (6)	14 Feb 2021 15:52:57
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	05 Feb 2021 02:08:51

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:37:16
Signature has been broken.	Cassie Uminski (b) (4)	25 Mar 2021 13:39:07
User signature succeeded.	(b) (4) Mary Beth Manning	09 Mar 2021 04:23:48
User entered '12 Jan 2021'	(b) (4) Jennifer Gaston (b) (4)	02 Mar 2021 16:46:37

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:37:16
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:38:49
User entered 'Anterior Cervical Discectomy/Decompression' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:38:49
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:23:48
User entered 'Herniated Disc Repair'	Jennifer Gaston (b) (4) (b) (4)	02 Mar 2021 16:46:37

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 19:37:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered 'Adverse Event (AE)'	Jennifer Gaston (b) (4)	02 Mar 2021 16:46:37
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 19:37:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	02 Mar 2021 16:46:37
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:30:11

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'CBC Panel'	Cassie Uminski (b) (4)	25 Mar 2021 13:30:11

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:34:32
User entered 'Adverse Event (AE)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:30:11
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:03
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	25 Mar 2021 13:30:11
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:06
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:30:42

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:06
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'CMP Panel'	Cassie Uminski (b) (4)	25 Mar 2021 13:30:42

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:06
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 13:34:40
User entered 'Adverse Event (AE)'	Cassie Uminski (b) (4)	25 Mar 2021 13:30:42
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:06
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	25 Mar 2021 13:30:42
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:31:15

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'COAG Panel'	Cassie Uminski (b) (4)	25 Mar 2021 13:31:15

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:34:47
User entered 'Adverse Event (AE)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:31:15
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	25 Mar 2021 13:31:15
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:31:38

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Type and screen Labs'	Cassie Uminski (b) (4)	25 Mar 2021 13:31:38

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 13:35:26
User entered 'Adverse Event (AE)'	Cassie Uminski (b) (4)	25 Mar 2021 13:31:38
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:13
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:31:38
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:16
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:33:29

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:16
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Chest X-Ray'	Cassie Uminski (b) (4)	25 Mar 2021 13:33:29

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:16
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:35:34
User entered 'Adverse Event (AE)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:33:29
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:16
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	25 Mar 2021 13:33:29
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:33:47

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'CT (PE)'	Cassie Uminski (b) (4)	25 Mar 2021 13:33:47

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 13:35:41
User entered 'Adverse Event (AE)'	Cassie Uminski (b) (4)	25 Mar 2021 13:33:47
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 13:33:47

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '16 Jan 2021'	Cassie Uminski (b) (4)	25 Mar 2021 13:36:03

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'CT (neck)'	Cassie Uminski	25 Mar 2021 13:36:03

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)'	Cassie Uminski (b) (4)	25 Mar 2021 13:36:03

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	25 Mar 2021 13:36:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:33:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered '12 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 16:38:30
DataPoint activated with code reason code Data required.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 16:38:10
DataPoint inactivated with code reason code Data not required.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 13:39:07

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:33:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'X-ray'	Cassie Uminski (b) (4)	25 Mar 2021 16:38:30
DataPoint activated with code reason code Data required.	Cassie Uminski (b) (4)	25 Mar 2021 16:38:10
DataPoint inactivated with code reason code Data not required.	Cassie Uminski (b) (4)	25 Mar 2021 13:39:07

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:33:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 16:38:30
DataPoint activated with code reason code Data required.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 16:38:10
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 13:39:07
	(b) (4)	

US3182158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:33:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:27
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 16:38:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Cassie Uminski (b) (4)	25 Mar 2021 16:38:10
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Cassie Uminski (b) (4)	25 Mar 2021 13:39:07
	(b) (4)	

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered	System	27 Jan 2021 18:11:22
'USA-US075-2021-MRNA-1273-P301000004'		

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Jennifer'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Gaston'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '3619 Park East Drive, Suite 300'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered 'Beachwood'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'OH'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '44122'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:08:18
User entered 'US'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:14:46
User entered '4'	System	26 Mar 2021 17:03:56
User entered '3'	System	03 Mar 2021 16:17:19
User entered '2'	System	23 Feb 2021 20:08:32
User entered '1'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered	System	27 Jan 2021 18:11:22
'USA-US075-2021-MRNA-1273-P301000004'		

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Jennifer'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Gaston'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '3619 Park East Drive, Suite 300'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered 'Beachwood'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'OH'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '44122'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:08:18
User entered 'US'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:14:46
User entered '4'	System	26 Mar 2021 17:03:56
User entered '3'	System	03 Mar 2021 16:17:19
User entered '2'	System	23 Feb 2021 20:08:32
User entered '1'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered '27/Jan/2021 18:11'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:21

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)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:08:18
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered	System	27 Jan 2021 18:11:22
'USA-US075-2021-MRNA-1273-P301000004'		

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Jennifer'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Gaston'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '3619 Park East Drive, Suite 300'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered 'Beachwood'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'OH'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '44122'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:08:18
User entered 'US'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:14:46
User entered '4'	System	26 Mar 2021 17:03:56
User entered '3'	System	03 Mar 2021 16:17:19
User entered '2'	System	23 Feb 2021 20:08:32
User entered '1'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered '23/Feb/2021 15:08'	System	23 Feb 2021 20:08:32

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:21

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)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 20:08:32

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered	System	27 Jan 2021 18:11:22
'USA-US075-2021-MRNA-1273-P301000004'		

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Jennifer'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Gaston'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '3619 Park East Drive, Suite 300'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered 'Beachwood'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'OH'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '44122'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:08:18
User entered 'US'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:14:46
User entered '4'	System	26 Mar 2021 17:03:56
User entered '3'	System	03 Mar 2021 16:17:19
User entered '2'	System	23 Feb 2021 20:08:32
User entered '1'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:33:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
User entered '03/Mar/2021 10:17'	System	03 Mar 2021 16:17:19

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:33:21

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)	15 Apr 2021 12:37:15
Reviewed for Safety.		08 Apr 2021 16:14:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:17:19

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered	System	27 Jan 2021 18:11:22
'USA-US075-2021-MRNA-1273-P301000004'		

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Jennifer'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Gaston'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '3619 Park East Drive, Suite 300'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered 'Beachwood'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'OH'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '44122'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:08:18
User entered 'US'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:14:46
User entered '4'	System	26 Mar 2021 17:03:56
User entered '3'	System	03 Mar 2021 16:17:19
User entered '2'	System	23 Feb 2021 20:08:32
User entered '1'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:33:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered '26/Mar/2021 13:03'	System	26 Mar 2021 17:03:56

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:33:21

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)	15 Apr 2021 12:37:15
Reviewed for Safety.		08 Apr 2021 16:14:21
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:03:56

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered	System	27 Jan 2021 18:11:22
'USA-US075-2021-MRNA-1273-P301000004'		

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Yes (Y)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'No (N)'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Jennifer'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:14:46
Signature has been broken.	System	08 Apr 2021 16:14:46
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'Gaston'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '3619 Park East Drive, Suite 300'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered 'Beachwood'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:11:44
User entered 'OH'	System	27 Jan 2021 18:11:22

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '44122'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:23:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:08:18
User entered 'US'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 16:14:46
User entered '4'	System	26 Mar 2021 17:03:56
User entered '3'	System	03 Mar 2021 16:17:19
User entered '2'	System	23 Feb 2021 20:08:32
User entered '1'	System	27 Jan 2021 18:11:53

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:33:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered '08/Apr/2021 12:14'	System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:33:21

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)	15 Apr 2021 12:37:15
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered	(b) (4)	26 Mar 2021 17:06:50
'USA-US075-2021-MRNA-1273-P301000011'	System	

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'Yes (Y)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'Yes (Y)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
Signature has been broken.	(b) (4)	
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	System	08 Apr 2021 16:14:46
	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered 'Jennifer'	System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
Signature has been broken.	(b) (4)	
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	System	08 Apr 2021 16:14:46
	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered 'Gaston'	System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered 'Beachwood'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'OH'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered '44122'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'US'	(b) (4) System	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 17:19:00
User entered '1'	System	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered	(b) (4)	26 Mar 2021 17:06:50
'USA-US075-2021-MRNA-1273-P301000011'	System	

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'Yes (Y)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'Yes (Y)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
Signature has been broken.	(b) (4)	
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	System	08 Apr 2021 16:14:46
	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered 'Jennifer'	System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
Signature has been broken.	(b) (4)	
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	System	08 Apr 2021 16:14:46
	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered 'Gaston'	System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered 'Beachwood'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'OH'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered '44122'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'US'	(b) (4) System	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 17:19:00
User entered '1'	System	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered '26/Mar/2021 13:07'	System	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:21

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)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered	(b) (4)	26 Mar 2021 17:06:50
'USA-US075-2021-MRNA-1273-P301000011'	System	

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'Yes (Y)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'Yes (Y)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'No (N)'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
Signature has been broken.	(b) (4)	
User entered 'Toby'	System	08 Apr 2021 16:14:46
User signature succeeded.	System	08 Apr 2021 16:14:46
	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered 'Jennifer'	System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
Signature has been broken.	(b) (4)	
User entered 'Briskin'	System	08 Apr 2021 16:14:46
User signature succeeded.	System	08 Apr 2021 16:14:46
	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered 'Gaston'	System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered 'Beachwood'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'OH'	(b) (4) System	26 Mar 2021 17:06:50

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:32
User entered '44122'	(b) (4) System	08 Apr 2021 16:14:46

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
Reviewed for Safety.		08 Apr 2021 17:18:46
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
User entered 'US'	(b) (4) System	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 17:19:00
User entered '1'	System	26 Mar 2021 17:07:17

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:37:25
User signature succeeded.	Mary Beth Manning	09 Apr 2021 15:31:21
	(b) (4)	
User entered '08/Apr/2021 13:18'	System	08 Apr 2021 17:19:00

US3182158

Folder: SAE USA-US075-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:21

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)	15 Apr 2021 12:37:25
User signature succeeded.	Mary Beth Manning	09 Apr 2021 15:31:21
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 17:19:00