

US3182166 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:34:19

All time stamps listed in this document are displayed in GMT

US3182166

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

[Participant ID](#)

US3182166

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

US3182166

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

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

Visit date (dd MMM yyyy)	05 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3182166

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:40:50

Generated On: 09 Jun 2021 15:34:19

Date of Birth (MMM yyyy)	(b) (6) 1940
Age	80
Age Units	YEARS
Age (Derived)	80
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

US3182166

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:40:50

Generated On: 09 Jun 2021 15:34:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	5 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

US3182166

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:40:50

Generated On: 09 Jun 2021 15:34:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3182166

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Were any significant conditions reported?

Yes ☒

No ☐

US3182166

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3182166

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	BILATERAL HYPEROPIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3182166

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	HEART ATTACK
Start date (dd MMM yyyy)	14 JAN 2020
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)	14 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

US3182166

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	14 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3182166

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3182166

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	STENT PLACEMENT-LAD
Start date (dd MMM yyyy)	15 JAN 2020
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)	15 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

US3182166

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	BRADYCARDIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182166

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	PACEMAKER
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3182166

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Condition	BILATERAL MACULAR DEGENERATION
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3182166

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	05 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:48 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 09:48
Height (<i>xxx.x</i>)	176.7 cm
Weight (<i>xxx.x</i>)	77.5 kg
BMI (<i>xxx.x</i>)	24.82153 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182166

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

US3182166

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

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

RETIRED; OCCASIONAL PART
TIME WORK OUT OF HOME.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3182166

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:40:51

Generated On: 09 Jun 2021 15:34:19

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	

US3182166

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 184636

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 ☒

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Height	ND - Not Done
Weight	ND - Not Done

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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)	05 AUG 2020
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 09:48
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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)	05 AUG 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 12:05
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3182166

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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.

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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) 5 AUG 2020

What was the treatment time? (00:00-23:59) 11:13 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 11:13

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

US3182166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 AUG 2020

Collection time (00:00-23:59)

10:37 (24 HR)

Collection date and time (derived)

05 AUG 2020 10:37

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Collection date (dd MMM yyyy)			05 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:26	05 AUG 2020 10:26
Nasopharyngeal Swab 2	No		

US3182166

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 11:59

PC Open Date & Time

05 AUG 2020 11:33

PC Close Date & Time

05 AUG 2020 14:03

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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	05 AUG 2020 20:54
PC Open Date & Time	05 AUG 2020 14:58
PC Close Date & Time	06 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 20:49

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 20:55

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 20:53

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 20:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 20:47

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 20:48

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

05 AUG 2020 12:01

PC Open Date & Time

05 AUG 2020 11:33

PC Close Date & Time

05 AUG 2020 14:03

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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

05 AUG 2020 20:56

PC Open Date & Time

05 AUG 2020 14:58

PC Close Date & Time

06 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

06 AUG 2020 20:50

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

07 AUG 2020 20:56

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

08 AUG 2020 20:54

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 20:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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

10 AUG 2020 20:48

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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

11 AUG 2020 20:48

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 12:02
PC Open Date & Time	05 AUG 2020 11:33
PC Close Date & Time	05 AUG 2020 14:03

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 20:57
PC Open Date & Time	05 AUG 2020 14:58
PC Close Date & Time	06 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

52 of 2008

EAB) (1725)

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:51
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

54 of 2008

EAB) (1725)

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 20:57
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

EAB) (1725)

56 of 2008

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 20:54
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

58 of 2008

EAB) (1725)

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:50
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2008

EAB) (1725)

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 20:48
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

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

62 of 2008

EAB) (1725)

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 20:49
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3182166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 09:33
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:54
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3182166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020

What was the treatment time? (00:00-23:59) 10:19 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 10:19

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

US3182166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

10:01 (24 HR)

Collection date and time (derived)

04 SEP 2020 10:01

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:40	04 SEP 2020 09:40
Nasopharyngeal Swab 2	No		

US3182166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 10:50

PC Open Date & Time

04 SEP 2020 10:39

PC Close Date & Time

04 SEP 2020 13:09

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 98.3 °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	04 SEP 2020 20:28
PC Open Date & Time	04 SEP 2020 14:04
PC Close Date & Time	05 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.0 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 SEP 2020 19:53

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:15

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

97.2 °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

08 SEP 2020 20:25

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

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

97.5 °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

09 SEP 2020 20:38

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 7

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 20:25

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 10:52

PC Open Date & Time

04 SEP 2020 10:39

PC Close Date & Time

04 SEP 2020 13:09

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020 20:29

PC Open Date & Time

04 SEP 2020 14:04

PC Close Date & Time

05 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020 19:55

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020 20:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020 20:15

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020 20:25

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020 20:38

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 SEP 2020 20:26

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 10:52
PC Open Date & Time	04 SEP 2020 10:39
PC Close Date & Time	04 SEP 2020 13:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:30
PC Open Date & Time	04 SEP 2020 14:04
PC Close Date & Time	05 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 ☒

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:57
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

100 of 2008

EAB) (1725)

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

EAB) (1725)

102 of 2008

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:15
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

EAB) (1725)

104 of 2008

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 2008

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:39
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 ☒

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:26
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3182166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:18:25

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:13:13

Generated On: 09 Jun 2021 15:34:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	09:06 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 09:06
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

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.

US3182166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 OCT 2020

Collection time (00:00-23:59)

09:27 (24 HR)

Collection date and time (derived)

05 OCT 2020 09:27

US3182166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:13:12

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 11:25:40

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

15 OCT 2020 20:47:00

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

22 OCT 2020 23:00:38

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 18:34:39

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

01 JAN 2021 05:08:19

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

19 JAN 2021 15:43:12

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

22 JAN 2021 00:02:13

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 187

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

05 MAR 2021 00:01:47

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

12 MAR 2021 07:11:23

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

19 MAR 2021 18:52:24

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 03:24:17

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

06 APR 2021 11:31:03

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

09 APR 2021 13:19:44

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 <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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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°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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐ 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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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="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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
---	-------------------

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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°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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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°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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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="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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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="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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐
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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 <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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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°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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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"/>

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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°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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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 ☐
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 ☐

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3182166

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:34:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 09:07:36

US3182166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182166

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 11 Mar 2021 22:13:10

Generated On: 09 Jun 2021 15:34:19

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

Visit date (dd MMM yyyy)	18 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
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US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:53:59

Generated On: 09 Jun 2021 15:34:19

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) _____

US3182166

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 11 Mar 2021 22:13:10

Generated On: 09 Jun 2021 15:34:19

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.

US3182166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 11 Mar 2021 22:13:10

Generated On: 09 Jun 2021 15:34:19

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

Collection date (dd MMM yyyy)	18 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:55 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	18 FEB 2021 09:55
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US3182166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 22:13:10

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 15:47:21

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:47:21

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182166

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182166

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:34:19

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"/>

US3182166

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:34:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3182166

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:24:31

Generated On: 09 Jun 2021 15:34:19

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

Visit date (dd MMM yyyy)	25 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3182166

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

Form: Unblinding

Data signed: (b) (4) 11 Mar 2021 22:13:10

Generated On: 09 Jun 2021 15:34:19

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3182166

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

25 JAN 2021 10:40

US3182166

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

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

Collection date (dd MMM yyyy)	25 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	10:25
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Collection Date and Time (derived)	25 JAN 2021 10:25
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US3182166

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

AEID USA-US075-2021-MRNA-1273-P30
1000007

Adverse event GENERAL CHEST PAIN
SECONDARY TO SMALL CELL
CARCINOMA

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) 21 NOV 2020

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 21 NOV 2020

End time (00:00-23:59) _____

AE End Date and Time (derived) _____

Severity Grade 1/Mild ☐
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☒

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 21 NOV 2020

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2008

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

LATE ENTRY: SUBJECT
REPORTS THAT ON NOVEMBER
21, 2020 HE HAD AN EPISODE OF
CHEST PAIN, WHICH
PROMPTED HIM TO PRESENT
TO THE ER. SUBJECT HAD
SOME ASSOCIATED
DIFFICULTY BREATHING, AND
GIVEN HIS PRIOR HX OF MI
(HEART ATTACK), SUBJECT
WAS HOSPITALIZED TO
RULE-OUT ANOTHER MI.
ALTHOUGH HIS TROPONIN
CARDIAC MARKERS CAME
BACK ELEVATED, HIS
ANGIOGRAM, ECHO, AND PET
SCAN CAME BACK NEGATIVE
FOR AN MI, BUT IT DID SHOW
EVIDENCE OF MEDIASTINAL
MASS, WHICH IS PRESUMED TO
BE SECONDARY TO LYMPH
NODE INFECTION
(LYMPHADENOPATHY).

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)	

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

AEID	
Adverse event	FEVER
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)	04 APR 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)	04 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2008

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

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)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

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

Yes ☒

No ☐

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

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 80

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

349 of 2008

EAB) (1725)

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	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 JAN 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"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	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 2005	
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"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION/CORONARY
ARTERY DISEASE

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JAN 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication TICAGRELOR

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 90

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)

355 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	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 JAN 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 2

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)

357 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

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

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication OCUVITE (VITAMIN C, VITAMIN D, VITAMIN E, ZINC, COPPER, OMEGA 3 FATTY ACIDS, LUTEIN, ZEAXANTHIN ISOMERS)

Prophylaxis Yes ☐ No ☒

Indication MACULAR DEGENERATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1200

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)

363 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	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 JAN 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"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE
PAIN/HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	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)		05 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)		05 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2008

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

	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)		19 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)		19 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"/>

US3182166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:24:30

Generated On: 09 Jun 2021 15:34:19

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3182166

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:19

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 ☐

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 20:00:06

Generated On: 09 Jun 2021 15:34:19

SAEID	USA-US075-2021-MRNA-1273-P301000007
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

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 20:00:06

Generated On: 09 Jun 2021 15:34:19

SAEID	USA-US075-2021-MRNA-1273-P301000007
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)	22/FEB/2021 10:04
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

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 20:00:06

Generated On: 09 Jun 2021 15:34:19

SAEID	USA-US075-2021-MRNA-1273-P301000007
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 18:13
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

US3182166 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182166

Form: Participant Creation

Generated On: 09 Jun 2021 15:34:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'US3182166'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:14:44

US3182166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	05 Aug 2020 15:22:30

US3182166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:14:45

US3182166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Clinic (Clinic)'	Brooke Glivar (b) (4)	05 Aug 2020 15:22:30

US3182166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'SCRN'	System	05 Aug 2020 15:22:30

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered (b) (6) 1940'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:14:46

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '80'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:42:44

(b)

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'YEARS'	System	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '80'	System	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Male (M)'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'I'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	(b) (4)	11 Aug 2020 18:42:44
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4)	11 Aug 2020 18:42:44
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:42:44

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '5 Aug 2020'	Brooke Glivar (b) (4)	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Aug 2020'	System	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2020'	System	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Amendment 1 (1)'	Brooke Glivar (b) (4)	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	Brooke Glivar (b) (4)	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	Brooke Glivar (b) (4)	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	Brooke Glivar (b) (4)	05 Aug 2020 15:22:46

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:14:45

US3182166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'I'	System	05 Aug 2020 15:22:53

US3182166

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	05 Aug 2020 15:22:53

US3182166

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:34:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:08

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:54:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:54:17
Data point term sent to Coder	System	11 Aug 2020 18:53:20
User entered 'Chronic obstructive pulmonary disease'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2011'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2011'	System	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2011'	System	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:52:49

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User closed query 'Per DM CLR: Please specify the eye laterality with HYPEROPIA. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 05:03:39
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:57:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:57:56
Data point term sent to Coder	System	10 Sep 2020 15:57:12
Query 'Per DM CLR: Please specify the eye laterality with HYPEROPIA. Review and update Med History eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:56:40
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:56:36
User entered 'Bilateral HYPEROPIA' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:56:36
User opened query 'Per DM CLR: Please specify the eye laterality with HYPEROPIA. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 05:32:48
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:54:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:54:19
Data point term sent to Coder	System	11 Aug 2020 18:53:21
User entered 'Hyperopia'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2017'	Cassie Uminski	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4)	11 Aug 2020 18:52:59
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2017'	System	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2017'	System	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:52:59

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:54:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:54:16
Data point term sent to Coder	System	11 Aug 2020 18:53:21
User entered 'Heart Attack'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '14 Jan 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '14 Jan 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2020'	System	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2020'	System	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2020'	System	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2020'	System	11 Aug 2020 18:53:14

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:55:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:55:16
Data point term sent to Coder	System	11 Aug 2020 18:54:24
User entered 'Coronary Artery Disease'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '14 Jan 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4) Cassie Uminski (b) (4)	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2020'	System	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2020'	System	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:53:25

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
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)	11 Aug 2020 18:55:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:55:15
Data point term sent to Coder	System	11 Aug 2020 18:54:24
User entered 'High Cholesterol'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2005'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4)	11 Aug 2020 18:53:35
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2005'	System	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2005'	System	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:53:35

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:55:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:55:44
Data point term sent to Coder	System	11 Aug 2020 18:54:25
User entered 'Hypertension'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2010'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2010'	System	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2010'	System	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:53:52

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:55:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:55:16
Data point term sent to Coder	System	11 Aug 2020 18:54:25
User entered 'Depression'	Cassie Uminski (b) (4)	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2010'	Cassie Uminski	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Cassie Uminski	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4)	11 Aug 2020 18:54:03
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2010'	System	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2010'	System	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:54:03

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
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 arterial stent insertion - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 11:17:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 11:17:42
Data point term sent to Coder	System	11 Aug 2020 18:56:30
User entered 'Stent placement-LAD'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '15 Jan 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '15 Jan 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2020'	System	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2020'	System	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2020'	System	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2020'	System	11 Aug 2020 18:55:31

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:57:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:57:16
Data point term sent to Coder	System	11 Aug 2020 18:56:30
User entered 'Bradycardia'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2015'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2015'	System	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2015'	System	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:55:42

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 18:57:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:57:15
Data point term sent to Coder	System	11 Aug 2020 18:56:30
User entered 'Pacemaker'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2015'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4)	11 Aug 2020 18:55:56
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2015'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2015'	System	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2015'	System	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2015'	System	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2015'	System	11 Aug 2020 18:55:56

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User closed query 'Per DM CLR: Please specify the eye laterality with MACULAR DEGENERATION. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:31:09
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Macular degeneration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 12:53:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 12:53:44
Data point term sent to Coder	System	16 Sep 2020 12:52:25
Query 'Per DM CLR: Please specify the eye laterality with MACULAR DEGENERATION. Review and update Med History eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	16 Sep 2020 12:51:39
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	16 Sep 2020 12:51:35
User entered 'Bilateral MACULAR DEGENERATION' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	16 Sep 2020 12:51:35
User opened query 'Per DM CLR: Please specify the eye laterality with MACULAR DEGENERATION. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 05:33:12
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Macular degeneration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:57:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:57:16
Data point term sent to Coder	System	11 Aug 2020 18:56:31
User entered 'Macular degeneration'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'un UNK 2019'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'Jan 2019'	System	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '2019'	System	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered empty.	System	11 Aug 2020 18:56:19

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '05 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '09:48'	Cassie Uminski (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered '05 Aug 2020 09:48'	System	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '176.7' cm	(b) (4) Cassie Uminski (b) (4)	11 Aug 2020 18:44:17
DataPoint set to visible.	(b) (4) System	05 Aug 2020 15:22:53

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '77.5' kg	(b) (4) Cassie Uminski (b) (4)	11 Aug 2020 18:44:17
DataPoint set to visible.	(b) (4) System	05 Aug 2020 15:22:53

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
Amendment Manager: User entered '24.82153'	System	16 Sep 2020 23:43:43
User entered '24.8'	System	11 Aug 2020 18:44:17
DataPoint set to visible.	System	05 Aug 2020 15:22:53

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'kg/m2'	System	11 Aug 2020 18:44:17
DataPoint set to visible.	System	05 Aug 2020 15:22:53

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
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)	14 Sep 2020 05:03:12
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:55:59
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:55:54
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 05:06:06
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'bpm'	System	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'breaths/min'	System	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'mmHg'	System	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User entered 'mmHg'	System	11 Aug 2020 18:44:17

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40

US3182166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40

US3182166

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:37

US3182166

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
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)	13 Sep 2020 14:36:38
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 16:00:08
User entered '05 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:37

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4)	11 Aug 2020 18:51:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	11 Aug 2020 18:51:38
	(b) (4)	

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

[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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4)	11 Aug 2020 18:51:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

[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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4)	11 Aug 2020 18:51:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'Retired; occasional part time work out of home.'	Cassie Uminski (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered 'I'	(b) (4)	11 Aug 2020 18:51:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	(b) (4)	11 Aug 2020 18:51:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

[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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:51:38

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered '0'	(b) (4)	11 Aug 2020 18:51:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:35:40
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:40:51
User entered empty.	(b) (4)	11 Aug 2020 18:51:38
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	11 Aug 2020 18:46:38

US3182166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Aug 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:46:38

US3182166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[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 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	11 Aug 2020 18:46:38

US3182166

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'VISIT1'	System	11 Aug 2020 18:46:38

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 15:09:32

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:12:15
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:12:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 15:09:32
User entered '184636' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 15:09:32

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 15:09:32

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

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 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:26

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

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 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:26

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:26

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:26

US3182166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'No (N)'	Cassie Uminski	11 Aug 2020 18:45:26

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Aug 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '09:48'	(b) (4)	11 Aug 2020 18:45:05
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '05 Aug 2020 09:48'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '98.4' F	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05
	(b) (4)	

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '72'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'bpm'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '14'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'breaths/min'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '152'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '80'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Aug 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
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 18:38:22
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 18:45:05
User entered '12:05'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '05 Aug 2020 12:05'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Oct 2020 10:51:23
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per PI' (Site from System).	Brooke Glivar (b) (4) (b) (4)	09 Oct 2020 16:36:25
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:43:43
User entered '96.4' F	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Oral (Oral)'	(b) (4)	11 Aug 2020 18:45:05
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4)	11 Aug 2020 18:45:05
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '72'	(b) (4)	
	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05
	(b) (4)	

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'bpm'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '16'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'breaths/min'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '144'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '80'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	11 Aug 2020 18:45:05

US3182166

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:42

US3182166

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:45:42

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	Brooke Glivar (b) (4)	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	Brooke Glivar (b) (4)	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '5 Aug 2020'	Brooke Glivar (b) (4)	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '11:13'	Brooke Glivar (b) (4)	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered '5 Aug 2020 11:13'	System	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Left Arm (LEFT ARM)'	Brooke Glivar (b) (4)	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'ONCE'	System	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 15:23:14

US3182166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:46:23

US3182166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:46:23

US3182166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '10:37'	Cassie Uminski (b) (4)	11 Aug 2020 18:46:23

US3182166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered '05 Aug 2020 10:37'	System	11 Aug 2020 18:46:23

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:34:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Aug 2020'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:57
	(b) (4)	

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '10:26'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered '05 Aug 2020 10:26'	System	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered empty.	System	11 Aug 2020 18:45:57

US3182166

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	11 Aug 2020 18:46:28

US3182166

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	11 Aug 2020 18:46:28

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T11:57:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '373cce7f-16c9-484a-adb4-22d819d88531'	System	05 Aug 2020 15:59:22
User entered 'Yes (Y)'	System	05 Aug 2020 15:59:22

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T11:58:30', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '373cce7f-16c9-484a-adb4-22d819d88531'	System	05 Aug 2020 15:59:22
User entered '96.4'	System	05 Aug 2020 15:59:22

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T11:59:08', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '373cce7f-16c9-484a-adb4-22d819d88531'	System	05 Aug 2020 15:59:22
User entered 'No (N)'	System	05 Aug 2020 15:59:22

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T11:59:17', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '373cce7f-16c9-484a-adb4-22d819d88531'	System	05 Aug 2020 15:59:22
User entered '05 Aug 2020 11:59'	System	05 Aug 2020 15:59:22

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 11:33'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 14:03'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:54:10', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '081f7a4d-6b8e-45c5-8094-b019c7df2a81'	System	06 Aug 2020 00:54:58
User entered 'Yes (Y)'	System	06 Aug 2020 00:54:58

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:54:43', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '081f7a4d-6b8e-45c5-8094-b019c7df2a81'	System	06 Aug 2020 00:54:58
User entered '98.0'	System	06 Aug 2020 00:54:58

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:54:49', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '081f7a4d-6b8e-45c5-8094-b019c7df2a81'	System	06 Aug 2020 00:54:58
User entered 'No (N)'	System	06 Aug 2020 00:54:58

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:54:56', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '081f7a4d-6b8e-45c5-8094-b019c7df2a81'	System	06 Aug 2020 00:54:58
User entered '05 Aug 2020 20:54'	System	06 Aug 2020 00:54:58

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 14:58'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 2'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:48:48', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e60645-8e03-41ed-855f-cd6f69bc64be'	System	07 Aug 2020 00:49:44
User entered 'Yes (Y)'	System	07 Aug 2020 00:49:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:49:25', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e60645-8e03-41ed-855f-cd6f69bc64be'	System	07 Aug 2020 00:49:44
User entered '97.9'	System	07 Aug 2020 00:49:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:49:08', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e60645-8e03-41ed-855f-cd6f69bc64be'	System	07 Aug 2020 00:49:44
User entered 'No (N)'	System	07 Aug 2020 00:49:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:49:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e60645-8e03-41ed-855f-cd6f69bc64be'	System	07 Aug 2020 00:49:44
User entered '06 Aug 2020 20:49'	System	07 Aug 2020 00:49:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 3'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:54:42', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '76a6fa76-93b7-43eb-97f8-72d1b9351459'	System	08 Aug 2020 00:55:19
User entered 'Yes (Y)'	System	08 Aug 2020 00:55:19

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:54:52', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '76a6fa76-93b7-43eb-97f8-72d1b9351459'	System	08 Aug 2020 00:55:19
User entered '97.5'	System	08 Aug 2020 00:55:19

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:54:55', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '76a6fa76-93b7-43eb-97f8-72d1b9351459'	System	08 Aug 2020 00:55:19
User entered 'No (N)'	System	08 Aug 2020 00:55:19

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:55:16', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '76a6fa76-93b7-43eb-97f8-72d1b9351459'	System	08 Aug 2020 00:55:19
User entered '07 Aug 2020 20:55'	System	08 Aug 2020 00:55:19

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 4'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:52:55', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '910c46fc-6c66-4230-b6c8-f16eabe495f1'	System	09 Aug 2020 00:53:30
User entered 'Yes (Y)'	System	09 Aug 2020 00:53:30

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:53:14', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '910c46fc-6c66-4230-b6c8-f16eabe495f1' User entered '97.3'	System	09 Aug 2020 00:53:30
	System	09 Aug 2020 00:53:30

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:53:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '910c46fc-6c66-4230-b6c8-f16eabe495f1'	System	09 Aug 2020 00:53:30
User entered 'No (N)'	System	09 Aug 2020 00:53:30

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:53:25', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '910c46fc-6c66-4230-b6c8-f16eabe495f1'	System	09 Aug 2020 00:53:30
User entered '08 Aug 2020 20:53'	System	09 Aug 2020 00:53:30

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 5'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:02', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'ae408246-3eb3-4a97-8231-6f3f001b6b90'	System	10 Aug 2020 00:49:29
User entered 'Yes (Y)'	System	10 Aug 2020 00:49:29

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'ae408246-3eb3-4a97-8231-6f3f001b6b90'	System	10 Aug 2020 00:49:29
User entered '98.0'	System	10 Aug 2020 00:49:29

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'ae408246-3eb3-4a97-8231-6f3f001b6b90'	System	10 Aug 2020 00:49:29
User entered 'No (N)'	System	10 Aug 2020 00:49:29

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:23', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'ae408246-3eb3-4a97-8231-6f3f001b6b90'	System	10 Aug 2020 00:49:29
User entered '09 Aug 2020 20:49'	System	10 Aug 2020 00:49:29

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 6'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:47:13', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'a6ed59f3-a7a1-4735-9444-132e6112f8e2'	System	11 Aug 2020 00:47:44
User entered 'Yes (Y)'	System	11 Aug 2020 00:47:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:47:31', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'a6ed59f3-a7a1-4735-9444-132e6112f8e2'	System	11 Aug 2020 00:47:44
User entered '97.7'	System	11 Aug 2020 00:47:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:47:35', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'a6ed59f3-a7a1-4735-9444-132e6112f8e2'	System	11 Aug 2020 00:47:44
User entered 'No (N)'	System	11 Aug 2020 00:47:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:47:40', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'a6ed59f3-a7a1-4735-9444-132e6112f8e2'	System	11 Aug 2020 00:47:44
User entered '10 Aug 2020 20:47'	System	11 Aug 2020 00:47:44

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 7'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:10', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10c006be-4a32-461c-bc11-68849164745e'	System	12 Aug 2020 00:48:32
User entered 'Yes (Y)'	System	12 Aug 2020 00:48:32

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:18', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10c006be-4a32-461c-bc11-68849164745e' User entered '97.5'	System	12 Aug 2020 00:48:32
	System	12 Aug 2020 00:48:32

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:22', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10c006be-4a32-461c-bc11-68849164745e'	System	12 Aug 2020 00:48:32
User entered 'No (N)'	System	12 Aug 2020 00:48:32

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:27', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10c006be-4a32-461c-bc11-68849164745e'	System	12 Aug 2020 00:48:32
User entered '11 Aug 2020 20:48'	System	12 Aug 2020 00:48:32

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:00:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '397277bf-9c77-402c-ac30-71201bf7f22c'	System	05 Aug 2020 16:01:05
User entered 'None (1)'	System	05 Aug 2020 16:01:05

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:00:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '397277bf-9c77-402c-ac30-71201bf7f22c'	System	05 Aug 2020 16:01:05
User entered 'No (N)'	System	05 Aug 2020 16:01:05

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:00:23', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '397277bf-9c77-402c-ac30-71201bf7f22c'	System	05 Aug 2020 16:01:05
User entered 'No (N)'	System	05 Aug 2020 16:01:05

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:00:46', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '397277bf-9c77-402c-ac30-71201bf7f22c'	System	05 Aug 2020 16:01:05
User entered 'None (1)'	System	05 Aug 2020 16:01:05

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:01:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '397277bf-9c77-402c-ac30-71201bf7f22c'	System	05 Aug 2020 16:01:05
User entered '05 Aug 2020 12:01'	System	05 Aug 2020 16:01:05

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 11:33'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 14:03'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:16', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'd37541ac-5d03-46b5-8030-ecaa96f6a94d'	System	06 Aug 2020 00:56:45
User entered 'None (1)'	System	06 Aug 2020 00:56:45

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:21', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'd37541ac-5d03-46b5-8030-ecaa96f6a94d'	System	06 Aug 2020 00:56:45
User entered 'No (N)'	System	06 Aug 2020 00:56:45

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:26', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'd37541ac-5d03-46b5-8030-ecaa96f6a94d'	System	06 Aug 2020 00:56:45
User entered 'No (N)'	System	06 Aug 2020 00:56:45

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:35', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'd37541ac-5d03-46b5-8030-ecaa96f6a94d'	System	06 Aug 2020 00:56:45
User entered 'None (1)'	System	06 Aug 2020 00:56:45

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:41', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'd37541ac-5d03-46b5-8030-ecaa96f6a94d'	System	06 Aug 2020 00:56:45
User entered '05 Aug 2020 20:56'	System	06 Aug 2020 00:56:45

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 14:58'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 2'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:49:50', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '43b516dd-4f19-4bb5-a6f4-3d4468833436'	System	07 Aug 2020 00:50:40
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 00:50:40

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:50:04', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '43b516dd-4f19-4bb5-a6f4-3d4468833436'	System	07 Aug 2020 00:50:40
User entered 'No (N)'	System	07 Aug 2020 00:50:40

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:50:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '43b516dd-4f19-4bb5-a6f4-3d4468833436'	System	07 Aug 2020 00:50:40
User entered 'No (N)'	System	07 Aug 2020 00:50:40

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:50:26', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '43b516dd-4f19-4bb5-a6f4-3d4468833436'	System	07 Aug 2020 00:50:40
User entered 'None (1)'	System	07 Aug 2020 00:50:40

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:50:37', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '43b516dd-4f19-4bb5-a6f4-3d4468833436'	System	07 Aug 2020 00:50:40
User entered '06 Aug 2020 20:50'	System	07 Aug 2020 00:50:40

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 3'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:55:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '95c7b110-7bae-47cb-bf9f-8e1592e5d0b9'	System	08 Aug 2020 00:56:29
User entered 'None (1)'	System	08 Aug 2020 00:56:29

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:02', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '95c7b110-7bae-47cb-bf9f-8e1592e5d0b9'	System	08 Aug 2020 00:56:29
User entered 'No (N)'	System	08 Aug 2020 00:56:29

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:06', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '95c7b110-7bae-47cb-bf9f-8e1592e5d0b9'	System	08 Aug 2020 00:56:29
User entered 'No (N)'	System	08 Aug 2020 00:56:29

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '95c7b110-7bae-47cb-bf9f-8e1592e5d0b9'	System	08 Aug 2020 00:56:29
User entered 'None (1)'	System	08 Aug 2020 00:56:29

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:26', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '95c7b110-7bae-47cb-bf9f-8e1592e5d0b9'	System	08 Aug 2020 00:56:29
User entered '07 Aug 2020 20:56'	System	08 Aug 2020 00:56:29

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 4'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:53:33', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5cfc3bc-1632-4c88-bb5b-d66991fc591e'	System	09 Aug 2020 00:54:09
User entered 'None (1)'	System	09 Aug 2020 00:54:09

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:53:45', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5cfc3bc-1632-4c88-bb5b-d66991fc591e'	System	09 Aug 2020 00:54:09
User entered 'No (N)'	System	09 Aug 2020 00:54:09

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:53:47', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5cfc3bc-1632-4c88-bb5b-d66991fc591e'	System	09 Aug 2020 00:54:09
User entered 'No (N)'	System	09 Aug 2020 00:54:09

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:53:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5cfc3bc-1632-4c88-bb5b-d66991fc591e'	System	09 Aug 2020 00:54:09
User entered 'None (1)'	System	09 Aug 2020 00:54:09

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:06', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5cfc3bc-1632-4c88-bb5b-d66991fc591e'	System	09 Aug 2020 00:54:09
User entered '08 Aug 2020 20:54'	System	09 Aug 2020 00:54:09

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 5'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:29', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9754202a-dffa-40c8-84e8-5f167088aa02'	System	10 Aug 2020 00:49:56
User entered 'None (1)'	System	10 Aug 2020 00:49:56

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9754202a-dffa-40c8-84e8-5f167088aa02'	System	10 Aug 2020 00:49:56
User entered 'No (N)'	System	10 Aug 2020 00:49:56

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:41', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9754202a-dffa-40c8-84e8-5f167088aa02'	System	10 Aug 2020 00:49:56
User entered 'No (N)'	System	10 Aug 2020 00:49:56

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:47', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9754202a-dffa-40c8-84e8-5f167088aa02'	System	10 Aug 2020 00:49:56
User entered 'None (1)'	System	10 Aug 2020 00:49:56

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:51', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9754202a-dffa-40c8-84e8-5f167088aa02'	System	10 Aug 2020 00:49:56
User entered '09 Aug 2020 20:49'	System	10 Aug 2020 00:49:56

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 6'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:47:52', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10eb11c9-0bbd-40eb-906b-8cb4ba022b2a'	System	11 Aug 2020 00:48:10
User entered 'None (1)'	System	11 Aug 2020 00:48:10

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:47:55', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10eb11c9-0bbd-40eb-906b-8cb4ba022b2a'	System	11 Aug 2020 00:48:10
User entered 'No (N)'	System	11 Aug 2020 00:48:10

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:47:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10eb11c9-0bbd-40eb-906b-8cb4ba022b2a'	System	11 Aug 2020 00:48:10
User entered 'No (N)'	System	11 Aug 2020 00:48:10

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:02', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10eb11c9-0bbd-40eb-906b-8cb4ba022b2a'	System	11 Aug 2020 00:48:10
User entered 'None (1)'	System	11 Aug 2020 00:48:10

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:06', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '10eb11c9-0bbd-40eb-906b-8cb4ba022b2a'	System	11 Aug 2020 00:48:10
User entered '10 Aug 2020 20:48'	System	11 Aug 2020 00:48:10

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 7'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:31', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '42176c7e-4319-4d1f-bb91-c89d1e05c6ed'	System	12 Aug 2020 00:48:50
User entered 'None (1)'	System	12 Aug 2020 00:48:50

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:35', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '42176c7e-4319-4d1f-bb91-c89d1e05c6ed'	System	12 Aug 2020 00:48:50
User entered 'No (N)'	System	12 Aug 2020 00:48:50

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '42176c7e-4319-4d1f-bb91-c89d1e05c6ed'	System	12 Aug 2020 00:48:50
User entered 'No (N)'	System	12 Aug 2020 00:48:50

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:41', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '42176c7e-4319-4d1f-bb91-c89d1e05c6ed'	System	12 Aug 2020 00:48:50
User entered 'None (1)'	System	12 Aug 2020 00:48:50

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:47', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '42176c7e-4319-4d1f-bb91-c89d1e05c6ed'	System	12 Aug 2020 00:48:50
User entered '11 Aug 2020 20:48'	System	12 Aug 2020 00:48:50

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:01:34', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered 'None (0)'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:01:37', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered 'None (0)'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:01:41', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered 'None (0)'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:01:44', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered 'None (0)'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:01:54', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered 'None (0)'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:01:59', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered 'None (0)'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:02:06', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered 'No (N)'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T12:02:23', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b998739f-6f57-4244-ac5e-cc1587da6214'	System	05 Aug 2020 16:02:26
User entered '05 Aug 2020 12:02'	System	05 Aug 2020 16:02:26

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 11:33'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 14:03'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:49', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered 'None (0)'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:53', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered 'None (0)'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:56:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered 'None (0)'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:57:23', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered 'None (0)'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:57:28', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered 'None (0)'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:57:31', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered 'None (0)'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:57:34', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered 'No (N)'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-05T20:57:45', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '07db68ca-9273-4029-bbaf-f5fc85ea687f'	System	06 Aug 2020 00:57:48
User entered '05 Aug 2020 20:57'	System	06 Aug 2020 00:57:48

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Aug 2020 14:58'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 2'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:50:45', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered 'No interference with activity (1)'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:50:56', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered 'Some interference with activity (2)'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:51:01', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered 'None (0)'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:51:05', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered 'None (0)'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:51:08', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered 'None (0)'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:51:13', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered 'None (0)'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:51:17', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered 'No (N)'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-06T20:51:27', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8e13c89-c74d-4cc6-b570-706a47d30110'	System	07 Aug 2020 00:51:32
User entered '06 Aug 2020 20:51'	System	07 Aug 2020 00:51:32

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 3'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:33', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered 'None (0)'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:39', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered 'No interference with activity (1)'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:43', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered 'None (0)'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:50', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered 'None (0)'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:54', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered 'None (0)'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:56:59', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered 'None (0)'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:57:04', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered 'No (N)'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-07T20:57:16', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5b0d8ff0-b5fa-4cc3-9524-30d7a4cfbc23'	System	08 Aug 2020 00:57:20
User entered '07 Aug 2020 20:57'	System	08 Aug 2020 00:57:20

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 4'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered 'None (0)'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:22', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered 'None (0)'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:30', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered 'None (0)'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:43', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered 'None (0)'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:46', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered 'None (0)'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:49', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered 'None (0)'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:52', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered 'No (N)'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-08T20:54:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1d8bd21e-f3f0-4d69-97a4-a92c464d161d'	System	09 Aug 2020 00:55:02
User entered '08 Aug 2020 20:54'	System	09 Aug 2020 00:55:02

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 5'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:56', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered 'None (0)'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:49:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered 'None (0)'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:50:01', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered 'None (0)'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:50:04', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered 'None (0)'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:50:06', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered 'None (0)'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:50:09', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered 'None (0)'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:50:12', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered 'No (N)'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-09T20:50:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '021f5971-d469-4d5a-b468-f035120421b2'	System	10 Aug 2020 00:50:18
User entered '09 Aug 2020 20:50'	System	10 Aug 2020 00:50:18

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 6'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:12', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered 'None (0)'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered 'None (0)'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:18', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered 'None (0)'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:21', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered 'None (0)'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:24', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered 'None (0)'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:30', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered 'None (0)'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:33', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered 'No (N)'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-10T20:48:37', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '69c93930-11e3-40ca-b48a-9998dcc66511'	System	11 Aug 2020 00:48:40
User entered '10 Aug 2020 20:48'	System	11 Aug 2020 00:48:40

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 7'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:51', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered 'None (0)'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:55', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered 'None (0)'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:48:59', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered 'None (0)'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:49:02', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered 'None (0)'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:49:05', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered 'None (0)'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:49:27', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered 'None (0)'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:49:30', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered 'No (N)'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-08-11T20:49:36', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '080f2213-7a96-4548-8886-36ef03d2d862'	System	12 Aug 2020 00:49:38
User entered '11 Aug 2020 20:49'	System	12 Aug 2020 00:49:38

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 15:23:14

US3182166

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:10:03

US3182166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered '12 Aug 2020'	Alec Ireland (b) (4)	20 Aug 2020 14:10:03

US3182166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	20 Aug 2020 14:10:03

US3182166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:10:03

US3182166

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	Alec Ireland	20 Aug 2020 14:09:54

US3182166

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	20 Aug 2020 14:09:54

US3182166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:37:19

US3182166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered '19 Aug 2020'	Alec Ireland (b) (4)	24 Aug 2020 13:37:19

US3182166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	24 Aug 2020 13:37:19

US3182166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:37:19

US3182166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:37:23

US3182166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	24 Aug 2020 13:37:23

US3182166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:14:59

US3182166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered '26 Aug 2020'	Alec Ireland (b) (4)	26 Aug 2020 18:14:59

US3182166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	26 Aug 2020 18:14:59

US3182166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	26 Aug 2020 18:14:59

US3182166

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	Alec Ireland	26 Aug 2020 18:14:52

US3182166

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	26 Aug 2020 18:14:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Sep 2020 16:00:08

US3182166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '04 Sep 2020'	Cassie Uminski (b) (4)	10 Sep 2020 16:00:08

US3182166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[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 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	10 Sep 2020 16:00:08

US3182166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'VISIT2'	System	10 Sep 2020 16:00:08

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '04 Sep 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '09:33'	(b) (4)	10 Sep 2020 16:02:52
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '04 Sep 2020 09:33'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '98.5' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4)	10 Sep 2020 16:02:52
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '66'	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'bpm'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '16'	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'breaths/min'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '150'	(b) (4)	10 Sep 2020 16:02:52
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '81'	(b) (4)	
	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '04 Sep 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '10:54'	(b) (4)	10 Sep 2020 16:02:52
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '04 Sep 2020 10:54'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '97.7' F	(b) (4)	
	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Oral (Oral)'	(b) (4)	
	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4)	10 Sep 2020 16:02:52
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '67'	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'bpm'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'breaths/min'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '147'	(b) (4)	
	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '77'	Cassie Uminski (b) (4)	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	10 Sep 2020 16:02:52

US3182166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	(b) (4)	10 Sep 2020 16:04:12
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '04 Sep 2020'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:12

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4)	
	Amy Maroun (b) (4)	04 Sep 2020 14:27:31
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '4 Sep 2020'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '10:19'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '4 Sep 2020 10:19'	System	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amy Maroun (b) (4) (b) (4)	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'ONCE'	System	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 14:27:31

US3182166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	10 Sep 2020 16:04:40

US3182166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '04 Sep 2020'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:40

US3182166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '10:01'	(b) (4)	
	Cassie Uminski (b) (4)	10 Sep 2020 16:04:40
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '04 Sep 2020 10:01'	System	10 Sep 2020 16:04:40

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:34:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '04 Sep 2020'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:27

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:27
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:27

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '09:40'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:27

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '04 Sep 2020 09:40'	System	10 Sep 2020 16:04:27

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:27
	(b) (4)	

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 16:04:27

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4)	10 Sep 2020 16:04:27

US3182166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered empty.	System	10 Sep 2020 16:04:27

US3182166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Sep 2020 16:04:45

US3182166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'I'	System	10 Sep 2020 16:04:45

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:50:22', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'cf96733b-893b-487a-97f1-81deb53d644e'	System	04 Sep 2020 14:50:57
User entered 'Yes (Y)'	System	04 Sep 2020 14:50:57

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:50:32', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'cf96733b-893b-487a-97f1-81deb53d644e'	System	04 Sep 2020 14:50:57
User entered '97.7'	System	04 Sep 2020 14:50:57

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:50:42', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'cf96733b-893b-487a-97f1-81deb53d644e'	System	04 Sep 2020 14:50:57
User entered 'No (N)'	System	04 Sep 2020 14:50:57

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:50:54', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'cf96733b-893b-487a-97f1-81deb53d644e'	System	04 Sep 2020 14:50:57
User entered '04 Sep 2020 10:50'	System	04 Sep 2020 14:50:57

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 10:39'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 13:09'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:28:14', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '64d13bd2-cd7b-4ce4-8fda-23a68c7903dd'	System	05 Sep 2020 00:28:40
User entered 'Yes (Y)'	System	05 Sep 2020 00:28:40

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:28:27', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '64d13bd2-cd7b-4ce4-8fda-23a68c7903dd' User entered '98.3'	System	05 Sep 2020 00:28:40
	System	05 Sep 2020 00:28:40

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:28:32', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '64d13bd2-cd7b-4ce4-8fda-23a68c7903dd'	System	05 Sep 2020 00:28:40
User entered 'No (N)'	System	05 Sep 2020 00:28:40

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:28:37', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '64d13bd2-cd7b-4ce4-8fda-23a68c7903dd'	System	05 Sep 2020 00:28:40
User entered '04 Sep 2020 20:28'	System	05 Sep 2020 00:28:40

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 14:04'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 2'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:52:57', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e9aa9634-43c2-4234-bc33-84afccc6a371'	System	05 Sep 2020 23:53:51
User entered 'Yes (Y)'	System	05 Sep 2020 23:53:51

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:53:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e9aa9634-43c2-4234-bc33-84afccc6a371' User entered '100.0'	System	05 Sep 2020 23:53:51
	System	05 Sep 2020 23:53:51

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:53:24', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e9aa9634-43c2-4234-bc33-84afccc6a371'	System	05 Sep 2020 23:53:51
User entered 'Yes (Y)'	System	05 Sep 2020 23:53:51

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted and corrected' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 18:48:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Brooke Glivar (b) (4)	09 Oct 2020 16:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:53:36', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e9aa9634-43c2-4234-bc33-84afccc6a371'	(b) (4)	
User entered '1'	System	05 Sep 2020 23:53:51
	System	05 Sep 2020 23:53:51
	System	05 Sep 2020 23:53:51

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:53:36', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e9aa9634-43c2-4234-bc33-84afccc6a371'	System	05 Sep 2020 23:53:51
User entered '0'	System	05 Sep 2020 23:53:51

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:53:45', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e9aa9634-43c2-4234-bc33-84afccc6a371'	System	05 Sep 2020 23:53:51
User entered '05 Sep 2020 19:53'	System	05 Sep 2020 23:53:51

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 3'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T19:59:50', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '789f979a-b655-47fb-8183-63058f82a0f3'	System	07 Sep 2020 00:00:25
User entered 'Yes (Y)'	System	07 Sep 2020 00:00:25

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:00:08', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '789f979a-b655-47fb-8183-63058f82a0f3'	System	07 Sep 2020 00:00:25
User entered '98.6'	System	07 Sep 2020 00:00:25

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:00:13', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '789f979a-b655-47fb-8183-63058f82a0f3'	System	07 Sep 2020 00:00:25
User entered 'No (N)'	System	07 Sep 2020 00:00:25

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:00:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '789f979a-b655-47fb-8183-63058f82a0f3'	System	07 Sep 2020 00:00:25
User entered '06 Sep 2020 20:00'	System	07 Sep 2020 00:00:25

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 4'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:14:44', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7527d6f6-a9ca-4745-a61f-4486544de531'	System	08 Sep 2020 00:15:06
User entered 'Yes (Y)'	System	08 Sep 2020 00:15:06

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:14:52', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7527d6f6-a9ca-4745-a61f-4486544de531'	System	08 Sep 2020 00:15:06
User entered '96.5'	System	08 Sep 2020 00:15:06

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:14:55', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7527d6f6-a9ca-4745-a61f-4486544de531'	System	08 Sep 2020 00:15:06
User entered 'No (N)'	System	08 Sep 2020 00:15:06

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7527d6f6-a9ca-4745-a61f-4486544de531'	System	08 Sep 2020 00:15:06
User entered '07 Sep 2020 20:15'	System	08 Sep 2020 00:15:06

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 5'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:10', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '726e5347-f784-48ba-9943-c10ed3889fcc'	System	09 Sep 2020 00:25:31
User entered 'Yes (Y)'	System	09 Sep 2020 00:25:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:20', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '726e5347-f784-48ba-9943-c10ed3889fcc'	System	09 Sep 2020 00:25:31
User entered '97.2'	System	09 Sep 2020 00:25:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:23', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '726e5347-f784-48ba-9943-c10ed3889fcc'	System	09 Sep 2020 00:25:31
User entered 'No (N)'	System	09 Sep 2020 00:25:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:29', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '726e5347-f784-48ba-9943-c10ed3889fcc'	System	09 Sep 2020 00:25:31
User entered '08 Sep 2020 20:25'	System	09 Sep 2020 00:25:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 6'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:37:11', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '35d23cd8-81db-4128-bfa9-2e70197b5c9d'	System	10 Sep 2020 00:38:14
User entered 'Yes (Y)'	System	10 Sep 2020 00:38:14

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:01', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '35d23cd8-81db-4128-bfa9-2e70197b5c9d'	System	10 Sep 2020 00:38:14
User entered '97.5'	System	10 Sep 2020 00:38:14

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:06', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '35d23cd8-81db-4128-bfa9-2e70197b5c9d'	System	10 Sep 2020 00:38:14
User entered 'No (N)'	System	10 Sep 2020 00:38:14

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:11', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '35d23cd8-81db-4128-bfa9-2e70197b5c9d'	System	10 Sep 2020 00:38:14
User entered '09 Sep 2020 20:38'	System	10 Sep 2020 00:38:14

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 7'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:25:32', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3ba17d6a-b088-41ce-8c8f-d6c31bde2ecc'	System	11 Sep 2020 00:25:52
User entered 'Yes (Y)'	System	11 Sep 2020 00:25:52

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:25:43', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3ba17d6a-b088-41ce-8c8f-d6c31bde2ecc'	System	11 Sep 2020 00:25:52
User entered '97.6'	System	11 Sep 2020 00:25:52

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:25:46', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3ba17d6a-b088-41ce-8c8f-d6c31bde2ecc'	System	11 Sep 2020 00:25:52
User entered 'No (N)'	System	11 Sep 2020 00:25:52

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:25:48', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3ba17d6a-b088-41ce-8c8f-d6c31bde2ecc'	System	11 Sep 2020 00:25:52
User entered '10 Sep 2020 20:25'	System	11 Sep 2020 00:25:52

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:51:55', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '89caad59-fba9-4b5d-9e04-cc2618bf4d42'	System	04 Sep 2020 14:52:23
User entered 'None (1)'	System	04 Sep 2020 14:52:23

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '89caad59-fba9-4b5d-9e04-cc2618bf4d42'	System	04 Sep 2020 14:52:23
User entered 'No (N)'	System	04 Sep 2020 14:52:23

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:04', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '89caad59-fba9-4b5d-9e04-cc2618bf4d42'	System	04 Sep 2020 14:52:23
User entered 'No (N)'	System	04 Sep 2020 14:52:23

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:08', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '89caad59-fba9-4b5d-9e04-cc2618bf4d42'	System	04 Sep 2020 14:52:23
User entered 'None (1)'	System	04 Sep 2020 14:52:23

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:20', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '89caad59-fba9-4b5d-9e04-cc2618bf4d42'	System	04 Sep 2020 14:52:23
User entered '04 Sep 2020 10:52'	System	04 Sep 2020 14:52:23

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 10:39'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 13:09'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:28:49', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6d9d0bc1-dcc8-4d73-a476-003c33f49bb2'	System	05 Sep 2020 00:29:34
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 00:29:34

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:28:52', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6d9d0bc1-dcc8-4d73-a476-003c33f49bb2'	System	05 Sep 2020 00:29:34
User entered 'No (N)'	System	05 Sep 2020 00:29:34

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:05', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6d9d0bc1-dcc8-4d73-a476-003c33f49bb2'	System	05 Sep 2020 00:29:34
User entered 'No (N)'	System	05 Sep 2020 00:29:34

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:20', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6d9d0bc1-dcc8-4d73-a476-003c33f49bb2'	System	05 Sep 2020 00:29:34
User entered 'None (1)'	System	05 Sep 2020 00:29:34

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:31', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6d9d0bc1-dcc8-4d73-a476-003c33f49bb2'	System	05 Sep 2020 00:29:34
User entered '04 Sep 2020 20:29'	System	05 Sep 2020 00:29:34

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 14:04'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 2'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:54:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e778d5a5-d7f9-43b2-901d-4245576e8b69'	System	05 Sep 2020 23:55:09
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:55:09

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:54:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e778d5a5-d7f9-43b2-901d-4245576e8b69'	System	05 Sep 2020 23:55:09
User entered 'No (N)'	System	05 Sep 2020 23:55:09

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:54:22', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e778d5a5-d7f9-43b2-901d-4245576e8b69'	System	05 Sep 2020 23:55:09
User entered 'No (N)'	System	05 Sep 2020 23:55:09

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:54:33', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e778d5a5-d7f9-43b2-901d-4245576e8b69'	System	05 Sep 2020 23:55:09
User entered 'None (1)'	System	05 Sep 2020 23:55:09

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:55:04', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e778d5a5-d7f9-43b2-901d-4245576e8b69'	System	05 Sep 2020 23:55:09
User entered '05 Sep 2020 19:55'	System	05 Sep 2020 23:55:09

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 3'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:00:28', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9d7f07d1-211c-4ec3-884e-80f16994b0a6'	System	07 Sep 2020 00:01:24
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 00:01:24

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:00:32', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9d7f07d1-211c-4ec3-884e-80f16994b0a6'	System	07 Sep 2020 00:01:24
User entered 'No (N)'	System	07 Sep 2020 00:01:24

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:00:35', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9d7f07d1-211c-4ec3-884e-80f16994b0a6'	System	07 Sep 2020 00:01:24
User entered 'No (N)'	System	07 Sep 2020 00:01:24

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:01:12', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9d7f07d1-211c-4ec3-884e-80f16994b0a6'	System	07 Sep 2020 00:01:24
User entered 'None (1)'	System	07 Sep 2020 00:01:24

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:01:18', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9d7f07d1-211c-4ec3-884e-80f16994b0a6'	System	07 Sep 2020 00:01:24
User entered '06 Sep 2020 20:01'	System	07 Sep 2020 00:01:24

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 4'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:12', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e255e74f-a14d-43a2-ba82-27209d709c00'	System	08 Sep 2020 00:15:30
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 00:15:30

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:16', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e255e74f-a14d-43a2-ba82-27209d709c00'	System	08 Sep 2020 00:15:30
User entered 'No (N)'	System	08 Sep 2020 00:15:30

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:18', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e255e74f-a14d-43a2-ba82-27209d709c00'	System	08 Sep 2020 00:15:30
User entered 'No (N)'	System	08 Sep 2020 00:15:30

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:22', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e255e74f-a14d-43a2-ba82-27209d709c00'	System	08 Sep 2020 00:15:30
User entered 'None (1)'	System	08 Sep 2020 00:15:30

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:25', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'e255e74f-a14d-43a2-ba82-27209d709c00'	System	08 Sep 2020 00:15:30
User entered '07 Sep 2020 20:15'	System	08 Sep 2020 00:15:30

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 5'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:34', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e8d04c2-6092-4012-8183-63c99c4847cc'	System	09 Sep 2020 00:25:49
User entered 'None (1)'	System	09 Sep 2020 00:25:49

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e8d04c2-6092-4012-8183-63c99c4847cc'	System	09 Sep 2020 00:25:49
User entered 'No (N)'	System	09 Sep 2020 00:25:49

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:40', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e8d04c2-6092-4012-8183-63c99c4847cc'	System	09 Sep 2020 00:25:49
User entered 'No (N)'	System	09 Sep 2020 00:25:49

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:44', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e8d04c2-6092-4012-8183-63c99c4847cc'	System	09 Sep 2020 00:25:49
User entered 'None (1)'	System	09 Sep 2020 00:25:49

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:46', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e8d04c2-6092-4012-8183-63c99c4847cc'	System	09 Sep 2020 00:25:49
User entered '08 Sep 2020 20:25'	System	09 Sep 2020 00:25:49

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 6'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:28', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e7e8cac-bcc7-4df1-8b7d-11cc90cdc5d1'	System	10 Sep 2020 00:38:47
User entered 'None (1)'	System	10 Sep 2020 00:38:47

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:31', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e7e8cac-bcc7-4df1-8b7d-11cc90cdc5d1'	System	10 Sep 2020 00:38:47
User entered 'No (N)'	System	10 Sep 2020 00:38:47

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:36', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e7e8cac-bcc7-4df1-8b7d-11cc90cdc5d1'	System	10 Sep 2020 00:38:47
User entered 'No (N)'	System	10 Sep 2020 00:38:47

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e7e8cac-bcc7-4df1-8b7d-11cc90cdc5d1'	System	10 Sep 2020 00:38:47
User entered 'None (1)'	System	10 Sep 2020 00:38:47

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:44', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '3e7e8cac-bcc7-4df1-8b7d-11cc90cdc5d1'	System	10 Sep 2020 00:38:47
User entered '09 Sep 2020 20:38'	System	10 Sep 2020 00:38:47

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 7'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:25:53', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '22232c15-43da-4c52-948f-44b1347d0f40'	System	11 Sep 2020 00:26:08
User entered 'None (1)'	System	11 Sep 2020 00:26:08

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:25:56', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '22232c15-43da-4c52-948f-44b1347d0f40'	System	11 Sep 2020 00:26:08
User entered 'No (N)'	System	11 Sep 2020 00:26:08

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:25:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '22232c15-43da-4c52-948f-44b1347d0f40'	System	11 Sep 2020 00:26:08
User entered 'No (N)'	System	11 Sep 2020 00:26:08

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:01', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '22232c15-43da-4c52-948f-44b1347d0f40'	System	11 Sep 2020 00:26:08
User entered 'None (1)'	System	11 Sep 2020 00:26:08

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:04', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '22232c15-43da-4c52-948f-44b1347d0f40'	System	11 Sep 2020 00:26:08
User entered '10 Sep 2020 20:26'	System	11 Sep 2020 00:26:08

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:27', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered 'None (0)'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:30', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered 'None (0)'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:34', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered 'None (0)'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:37', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered 'None (0)'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:39', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered 'None (0)'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:41', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered 'None (0)'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:45', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered 'No (N)'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T10:52:49', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9ee448af-40e3-441f-a54d-6bf772c2119a'	System	04 Sep 2020 14:52:50
User entered '04 Sep 2020 10:52'	System	04 Sep 2020 14:52:50

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 10:39'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 13:09'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered 'None (0)'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:42', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered 'None (0)'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:45', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered 'None (0)'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:49', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered 'None (0)'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:52', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered 'None (0)'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:54', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered 'None (0)'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:29:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered 'No (N)'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-04T20:30:04', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '681383c0-2eba-4a49-ac62-d20ee4737b41'	System	05 Sep 2020 00:30:08
User entered '04 Sep 2020 20:30'	System	05 Sep 2020 00:30:08

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '04 Sep 2020 14:04'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 2'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:55:48', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:55:56', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered 'Some interference with activity (2)'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:56:05', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered 'Some interference with activity (2)'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:56:12', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered 'Some interference with activity (2)'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:56:18', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered 'None (0)'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:56:29', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:56:35', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered 'No (N)'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-05T19:57:31', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '6c5370d3-a0b6-4d66-85d5-0162045f26c8'	System	05 Sep 2020 23:57:33
User entered '05 Sep 2020 19:57'	System	05 Sep 2020 23:57:33

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 3'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:01:27', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:01:41', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered 'Some interference with activity (2)'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:01:51', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:01:57', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered 'None (0)'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:02:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered 'None (0)'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:02:03', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered 'None (0)'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:02:07', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered 'No (N)'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-06T20:02:10', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '7ed1b73a-a3aa-4b87-a95b-8da5c50ed5df'	System	07 Sep 2020 00:02:16
User entered '06 Sep 2020 20:02'	System	07 Sep 2020 00:02:16

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 4'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:29', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered 'None (0)'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:32', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:35', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered 'None (0)'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:37', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered 'None (0)'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:39', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered 'None (0)'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:41', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered 'None (0)'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:44', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered 'No (N)'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-07T20:15:47', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'b673658b-d64a-443c-a30d-7c478ba4abd8'	System	08 Sep 2020 00:15:52
User entered '07 Sep 2020 20:15'	System	08 Sep 2020 00:15:52

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 5'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:51', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered 'None (0)'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:53', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered 'None (0)'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:56', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered 'None (0)'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:25:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered 'None (0)'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:26:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered 'None (0)'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:26:02', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered 'None (0)'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:26:05', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered 'No (N)'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-08T20:26:08', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '1dfe86e5-0e4c-4641-a69e-de5fede64e9e'	System	09 Sep 2020 00:26:13
User entered '08 Sep 2020 20:26'	System	09 Sep 2020 00:26:13

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 6'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:49', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered 'None (0)'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:51', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered 'None (0)'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:53', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered 'None (0)'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:55', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered 'None (0)'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:38:58', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered 'None (0)'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:39:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered 'None (0)'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:39:03', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered 'No (N)'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-09T20:39:07', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '8af8a2c3-13dd-420b-9cf1-3fb697a0b347'	System	10 Sep 2020 00:39:09
User entered '09 Sep 2020 20:39'	System	10 Sep 2020 00:39:09

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	04 Sep 2020 14:27:31
User entered 'Day 7'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:08', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered 'None (0)'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:10', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered 'None (0)'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:13', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered 'None (0)'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:15', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered 'None (0)'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:17', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered 'None (0)'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered 'None (0)'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:23', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered 'No (N)'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-09-10T20:26:25', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '81d8842e-c58a-4f1f-9655-5aa8c9707bbe'	System	11 Sep 2020 00:26:31
User entered '10 Sep 2020 20:26'	System	11 Sep 2020 00:26:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:27:31

US3182166

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:27:31

US3182166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:00:48

US3182166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered '11 Sep 2020'	Alec Ireland (b) (4)	15 Sep 2020 18:00:48

US3182166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:00:48

US3182166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:00:48

US3182166

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:18:25
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:00:55

US3182166

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	15 Sep 2020 18:00:55

US3182166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	23 Sep 2020 15:58:25

US3182166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '18 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	23 Sep 2020 15:58:25

US3182166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	23 Sep 2020 15:58:25

US3182166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	23 Sep 2020 15:58:25

US3182166

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	23 Sep 2020 15:58:29

US3182166

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	23 Sep 2020 15:58:29

US3182166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	28 Sep 2020 12:58:30

US3182166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '25 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	28 Sep 2020 12:58:30

US3182166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	28 Sep 2020 12:58:30

US3182166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	28 Sep 2020 12:58:30

US3182166

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	28 Sep 2020 12:58:35

US3182166

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	28 Sep 2020 12:58:35

US3182166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	06 Oct 2020 15:32:45

US3182166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Oct 2020'	Cassie Uminski (b) (4)	06 Oct 2020 15:32:45

US3182166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[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 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	06 Oct 2020 15:32:45

US3182166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'VISIT3'	System	06 Oct 2020 15:32:45

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Oct 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '09:06'	Cassie Uminski (b) (4)	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '05 Oct 2020 09:06'	System	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '97.5' F	(b) (4)	
	Cassie Uminski (b) (4)	06 Oct 2020 15:33:00
	(b) (4)	

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	(b) (4)	06 Oct 2020 15:33:00
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '74'	Cassie Uminski (b) (4)	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'bpm'	System	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '14'	Cassie Uminski (b) (4)	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'breaths/min'	System	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '134'	(b) (4) Cassie Uminski (b) (4) (b) (4)	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '71'	Cassie Uminski (b) (4)	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'mmHg'	System	06 Oct 2020 15:33:00

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45

US3182166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45

US3182166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'No (N)'	Cassie Uminski	06 Oct 2020 15:33:06

US3182166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered empty.	Cassie Uminski (b) (4)	06 Oct 2020 15:33:06

US3182166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski	06 Oct 2020 15:33:14

US3182166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '05 Oct 2020'	Cassie Uminski (b) (4)	06 Oct 2020 15:33:14

US3182166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered '09:27'	(b) (4)	
	Cassie Uminski (b) (4)	06 Oct 2020 15:33:14
	(b) (4)	

US3182166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered '05 Oct 2020 09:27'	System	06 Oct 2020 15:33:14

US3182166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:13:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	06 Oct 2020 15:33:18

US3182166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:45
User entered 'I'	System	06 Oct 2020 15:33:18

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 64'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-08T11:25:29', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9e4f2132-beac-4429-b190-4592c6c4db2f'	System	08 Oct 2020 15:25:48
User entered 'No (N)'	System	08 Oct 2020 15:25:48

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-08T11:25:35', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9e4f2132-beac-4429-b190-4592c6c4db2f'	System	08 Oct 2020 15:25:48
User entered 'No (N)'	System	08 Oct 2020 15:25:48

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-08T11:25:40', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '9e4f2132-beac-4429-b190-4592c6c4db2f' User entered '08 Oct 2020 11:25:40'	System	08 Oct 2020 15:25:48
	System	08 Oct 2020 15:25:48

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 71'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-15T20:46:45', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '0ea0a017-f462-42fa-9467-68b9d723a90f'	System	16 Oct 2020 00:47:03
User entered 'No (N)'	System	16 Oct 2020 00:47:03

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-15T20:46:51', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '0ea0a017-f462-42fa-9467-68b9d723a90f'	System	16 Oct 2020 00:47:03
User entered 'No (N)'	System	16 Oct 2020 00:47:03

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-15T20:47:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '0ea0a017-f462-42fa-9467-68b9d723a90f' User entered '15 Oct 2020 20:47:00'	System	16 Oct 2020 00:47:03
	System	16 Oct 2020 00:47:03

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 78'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-22T23:00:25', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5316f98d-2790-42f7-8a6d-894aa115ea2c'	System	23 Oct 2020 03:01:23
User entered 'No (N)'	System	23 Oct 2020 03:01:23

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-22T22:59:36', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5316f98d-2790-42f7-8a6d-894aa115ea2c'	System	23 Oct 2020 03:01:23
User entered 'No (N)'	System	23 Oct 2020 03:01:23

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-10-22T23:00:38', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '5316f98d-2790-42f7-8a6d-894aa115ea2c'	System	23 Oct 2020 03:01:23
User entered '22 Oct 2020 23:00:38'	System	23 Oct 2020 03:01:23

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:09:09
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 92'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 99'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered 'Day 106'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15

US3182166

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 15:23:14

US3182166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:15:15
Data entry locked.	System	05 Aug 2020 15:23:14
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 15:23:14

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2020-12-27T18:34:20', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'eeb811bf-3c3c-4ffc-ba5a-2a7249731fa0'	System	27 Dec 2020 23:34:44
User entered 'No (N)'	System	27 Dec 2020 23:34:44

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2020-12-27T18:34:16', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'eeb811bf-3c3c-4ffc-ba5a-2a7249731fa0'	System	27 Dec 2020 23:34:44
User entered 'No (N)'	System	27 Dec 2020 23:34:44

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2020-12-27T18:34:39', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'eeb811bf-3c3c-4ffc-ba5a-2a7249731fa0'	System	27 Dec 2020 23:34:44
User entered '27 Dec 2020 18:34:39'	System	27 Dec 2020 23:34:44

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-01-01T05:08:05', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'a1828a69-ed67-45db-9358-3f5bbd477b39'	System	01 Jan 2021 10:08:23
User entered 'No (N)'	System	01 Jan 2021 10:08:23

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-01-01T05:08:11', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'a1828a69-ed67-45db-9358-3f5bbd477b39'	System	01 Jan 2021 10:08:23
User entered 'No (N)'	System	01 Jan 2021 10:08:23

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-01-01T05:08:19', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'a1828a69-ed67-45db-9358-3f5bbd477b39'	System	01 Jan 2021 10:08:23
User entered '01 Jan 2021 05:08:19'	System	01 Jan 2021 10:08:23

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-01-19T15:42:57', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '61bf55aa-f593-4169-a997-4f1794979a00'	System	19 Jan 2021 20:43:15
User entered 'No (N)'	System	19 Jan 2021 20:43:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-01-19T15:43:07', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '61bf55aa-f593-4169-a997-4f1794979a00'	System	19 Jan 2021 20:43:15
User entered 'No (N)'	System	19 Jan 2021 20:43:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-01-19T15:43:12', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '61bf55aa-f593-4169-a997-4f1794979a00'	System	19 Jan 2021 20:43:15
User entered '19 Jan 2021 15:43:12'	System	19 Jan 2021 20:43:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-01-22T00:02:02', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8d7cd04-b060-4127-a8e1-0c8dd077d803'	System	22 Jan 2021 05:02:20
User entered 'No (N)'	System	22 Jan 2021 05:02:20

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-01-22T00:02:06', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8d7cd04-b060-4127-a8e1-0c8dd077d803'	System	22 Jan 2021 05:02:20
User entered 'No (N)'	System	22 Jan 2021 05:02:20

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-01-22T00:02:13', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f8d7cd04-b060-4127-a8e1-0c8dd077d803'	System	22 Jan 2021 05:02:20
User entered '22 Jan 2021 00:02:13'	System	22 Jan 2021 05:02:20

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-03-05T00:01:34-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '326bd25d-173b-4467-a808-5dabe41cb279'	System	05 Mar 2021 05:02:53
User entered 'No (N)'	System	05 Mar 2021 05:02:53

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-03-05T00:01:42-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '326bd25d-173b-4467-a808-5dabe41cb279'	System	05 Mar 2021 05:02:53
User entered 'No (N)'	System	05 Mar 2021 05:02:53

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-03-05T00:01:47-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '326bd25d-173b-4467-a808-5dabe41cb279'	System	05 Mar 2021 05:02:53
User entered '05 Mar 2021 00:01:47'	System	05 Mar 2021 05:02:53

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-03-12T07:11:08-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '574af152-2b1e-4464-bb79-fc2c4ef41686'	System	12 Mar 2021 12:11:28
User entered 'No (N)'	System	12 Mar 2021 12:11:28

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-03-12T07:11:18-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '574af152-2b1e-4464-bb79-fc2c4ef41686'	System	12 Mar 2021 12:11:28
User entered 'No (N)'	System	12 Mar 2021 12:11:28

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-03-12T07:11:23-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '574af152-2b1e-4464-bb79-fc2c4ef41686'	System	12 Mar 2021 12:11:28
User entered '12 Mar 2021 07:11:23'	System	12 Mar 2021 12:11:28

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-03-19T18:52:16-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'bf75c7ee-edf9-4b84-8942-ec3eadc38415'	System	19 Mar 2021 22:52:28
User entered 'No (N)'	System	19 Mar 2021 22:52:28

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-03-19T18:52:20-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'bf75c7ee-edf9-4b84-8942-ec3eadc38415'	System	19 Mar 2021 22:52:28
User entered 'No (N)'	System	19 Mar 2021 22:52:28

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-03-19T18:52:24-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'bf75c7ee-edf9-4b84-8942-ec3eadc38415' User entered '19 Mar 2021 18:52:24'	System	19 Mar 2021 22:52:28

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-03-26T03:24:05-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5ebf002-a7ad-499c-b293-4e1f516b8520'	System	26 Mar 2021 07:24:23
User entered 'No (N)'	System	26 Mar 2021 07:24:23

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-03-26T03:24:11-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5ebf002-a7ad-499c-b293-4e1f516b8520'	System	26 Mar 2021 07:24:23
User entered 'No (N)'	System	26 Mar 2021 07:24:23

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-03-26T03:24:17-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f5ebf002-a7ad-499c-b293-4e1f516b8520'	System	26 Mar 2021 07:24:23
User entered '26 Mar 2021 03:24:17'	System	26 Mar 2021 07:24:23

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-04-06T11:30:55-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'caf5136f-175c-43ba-8eeb-e067107e35b0'	System	06 Apr 2021 15:31:06
User entered 'No (N)'	System	06 Apr 2021 15:31:06

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-04-06T11:30:59-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'caf5136f-175c-43ba-8eeb-e067107e35b0'	System	06 Apr 2021 15:31:06
User entered 'No (N)'	System	06 Apr 2021 15:31:06

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-04-06T11:31:03-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'caf5136f-175c-43ba-8eeb-e067107e35b0'	System	06 Apr 2021 15:31:06
User entered '06 Apr 2021 11:31:03'	System	06 Apr 2021 15:31:06

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[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 (9edd22f4567868c4)', Time: '2021-04-09T13:18:52-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '074a8519-ad52-4424-8445-93975679d326'	System	09 Apr 2021 17:19:51
User entered 'No (N)'	System	09 Apr 2021 17:19:51

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

Have you been exposed to someone with 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 (9edd22f4567868c4)', Time: '2021-04-09T13:18:54-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '074a8519-ad52-4424-8445-93975679d326'	System	09 Apr 2021 17:19:51
User entered 'No (N)'	System	09 Apr 2021 17:19:51

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-04-09T13:19:44-04:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: '074a8519-ad52-4424-8445-93975679d326'	System	09 Apr 2021 17:19:51
User entered '09 Apr 2021 13:19:44'	System	09 Apr 2021 17:19:51

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:15:15

US3182166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:15:15
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:15:15

US3182166

(b)

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:34:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-03-04T09:07:31-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f330fc7d-ed01-479f-bc05-b7f57b79df0b'	System	04 Mar 2021 14:07:39
User entered 'No (N)'	System	04 Mar 2021 14:07:39

US3182166

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:34:19

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:53:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9edd22f4567868c4)', Time: '2021-03-04T09:07:36-05:00', User OID: 'PatientReportedOutcome (US3182166)', ODM File OID: 'f330fc7d-ed01-479f-bc05-b7f57b79df0b'	System	04 Mar 2021 14:07:39
User entered '04 Mar 2021 09:07:36'	System	04 Mar 2021 14:07:39

US3182166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski	06 Nov 2020 17:47:48

US3182166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '29 Oct 2020'	Cassie Uminski	06 Nov 2020 17:47:48

US3182166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	06 Nov 2020 17:47:48

US3182166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	06 Nov 2020 17:47:48
	(b) (4)	

US3182166

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski	06 Nov 2020 17:49:25

US3182166

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:01:35
User entered 'I'	System	06 Nov 2020 17:49:25

US3182166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski	10 Dec 2020 02:57:34

US3182166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '01 Dec 2020'	Cassie Uminski (b) (4)	10 Dec 2020 02:57:34

US3182166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	10 Dec 2020 02:57:34

US3182166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4)	10 Dec 2020 02:57:34
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Dec 2020 02:57:50

US3182166

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered 'I'	System	10 Dec 2020 02:57:50

US3182166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Gabby Jacobs (b) (4)	31 Dec 2020 18:41:25

US3182166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '30 Dec 2020'	Gabby Jacobs (b) (4)	31 Dec 2020 18:41:25

US3182166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	31 Dec 2020 18:41:25

US3182166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4) Gabby Jacobs (b) (4) (b) (4)	31 Dec 2020 18:41:25

US3182166

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	31 Dec 2020 18:41:35

US3182166

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered 'I'	System	31 Dec 2020 18:41:35

US3182166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Feb 2021 15:57:50

US3182166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User closed query 'Per GCL Lab Recon: Immuno: Sample dated 18 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 21:06:42
Query 'Per GCL Lab Recon: Immuno: Sample dated 18 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	12 Mar 2021 21:08:52
User opened query 'Per GCL Lab Recon: Immuno: Sample dated 18 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:05:44
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 10:36:17
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Correct as is' (Site from System).	Cassie Uminski (b) (4) (b) (4)	28 Feb 2021 05:19:41
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Feb 2021 15:57:50
User entered '10 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	12 Feb 2021 15:57:50

US3182166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	12 Feb 2021 15:57:50

US3182166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	12 Feb 2021 15:57:50
	(b) (4)	

US3182166

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Feb 2021 16:04:25

US3182166

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered 'I'	System	12 Feb 2021 16:04:25

US3182166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Mar 2021 18:16:50

US3182166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered '18 Feb 2021'	Cassie Uminski (b) (4)	11 Mar 2021 18:16:50

US3182166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[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 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	11 Mar 2021 18:16:50

US3182166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered 'VISIT4'	System	11 Mar 2021 18:16:50

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered 'No (N)'	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered empty.	System	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered empty.	System	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered empty.	System	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered empty.	System	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:00
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered empty.	System	31 Mar 2021 14:14:27

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59

US3182166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59

US3182166

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Mar 2021 18:16:59

US3182166

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered empty.	Cassie Uminski (b) (4)	11 Mar 2021 18:16:59

US3182166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Mar 2021 18:17:40

US3182166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered '18 Feb 2021'	Cassie Uminski (b) (4)	11 Mar 2021 18:17:40

US3182166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered '09:55'	Cassie Uminski (b) (4)	11 Mar 2021 18:17:40

US3182166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered '18 Feb 2021 09:55'	System	11 Mar 2021 18:17:40

US3182166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Mar 2021 18:17:53

US3182166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:59
User entered 'I'	System	11 Mar 2021 18:17:53

US3182166

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:41
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:47:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 14:47:40

US3182166

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:41
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:47:21
User entered '30 Mar 2021'	Cassie Uminski (b) (4)	07 Apr 2021 14:47:40

US3182166

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:41
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:47:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 14:47:40

US3182166

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:41
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:47:21
User entered empty.	(b) (4)	07 Apr 2021 14:47:40
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:41
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:47:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 14:47:43

US3182166

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:41
User entered 'I'	System	07 Apr 2021 14:47:43

US3182166

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

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 19:34:58

US3182166

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

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '25 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 19:34:58

US3182166

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

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[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 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	28 Jan 2021 19:34:58

US3182166

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

Form: Visit Date

Generated On: 09 Jun 2021 15:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 19:34:58

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '25 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[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 22:59:25
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered '0'	Cassie Uminski (b) (4)	11 Mar 2021 18:18:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:17:36

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:13:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	Cassie Uminski (b) (4)	11 Mar 2021 18:18:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:17:36

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '25 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'mRNA-1273 (mRNA-1273)'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'mRNA-1273 (mRNA-1273)'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'mRNA-1273 (mRNA-1273)'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'No (N)'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User entered empty.	System	28 Jan 2021 19:35:10

US3182166

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

Form: Unblinding

Generated On: 09 Jun 2021 15:34:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User entered empty.	System	28 Jan 2021 19:35:10

US3182166

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:42

US3182166

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '25 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:42

US3182166

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '10:40'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:42

US3182166

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User entered '25 Jan 2021 10:40'	System	28 Jan 2021 19:35:42

US3182166

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:23

US3182166

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '25 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 19:35:23

US3182166

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '10:25'	(b) (4) Cassie Uminski (b) (4) (b) (4)	28 Jan 2021 19:35:23

US3182166

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:59:25
User entered '25 Jan 2021 10:25'	System	28 Jan 2021 19:35:23

US3182166

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:34:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:31:17
DataPoint Verified.		22 Apr 2021 12:23:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Feb 2021 21:51:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Feb 2021 02:15:16
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
Reviewed for Safety.	(b) (4)	22 Feb 2021 15:02:06
	(b) (4), (b) (6)	
User entered		22 Feb 2021 15:02:03
'USA-US075-2021-mRNA-1273-P301000007'	System	
User entered 'New'	(b) (4), (b) (6)	22 Feb 2021 15:02:03

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the cause for the chest pain (diagnosis) if available' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:07:30
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Neoplasm related morbidities, HLT: Oncologic complications and emergencies, PT: Cancer pain, LLT: Cancer pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 10:25:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:25:43
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:07:56
Data point term sent to Coder	System	25 Mar 2021 17:29:00
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' (Site from System).	System	25 Mar 2021 17:27:59
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' answered with 'Updated' (Site from System).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:27:59
Data point term sent to Coder	System	25 Mar 2021 17:27:56

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Updated-General Pain' (Site from DM).	Cassie Uminski (b) (4)	25 Mar 2021 17:27:55
Query 'PV Query: Please provide the cause for the chest pain (diagnosis) if available' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4)	25 Mar 2021 17:27:49
Coding entries removed.	Cassie Uminski (b) (4)	25 Mar 2021 17:27:01
User entered 'General CHEST PAIN secondary to small cell carcinoma' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 17:27:01
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ? ' (Site from System).	Coder Import (b) (4)	07 Mar 2021 16:06:09
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 01:31:29
User opened query 'PV Query: Please provide the cause for the chest pain (diagnosis) if available' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:27:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 22:00:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 22:00:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

1700 of 2008

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	17 Feb 2021 21:58:41
User entered 'Chest Pain'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Yes (Y)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'No (N)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'No (N)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '21 Nov 2020'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:08:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPdated' (Site from Safety).	Cassie Uminski (b) (4)	25 Mar 2021 17:29:46
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 17:29:39
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:28:32
User entered 'Yes (Y)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '21 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 17:29:39
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Mary Beth Manning (b) (4)	26 Mar 2021 18:08:06 26 Mar 2021 13:18:49
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:29:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). User entered empty.	(b) (4), (b) (6) Naqib Ahmad (b) (4) (b) (4)	26 Feb 2021 21:28:16 17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

Severity

Audit	User	Time (GMT)
User closed query 'Per completion guidelines severity should be grade 4 since they were hospitalized. ' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:36:15
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
Query 'Per completion guidelines severity should be grade 4 since they were hospitalized. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	25 Mar 2021 17:29:58
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Mar 2021 17:29:39
Query 'PV Query: Since the subject was hospitalized for the event of chest pain, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain. ' canceled (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 18:48:47
User opened query 'Per completion guidelines severity should be grade 4 since they were hospitalized. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 15:30:29
User opened query 'PV Query: Since the subject was hospitalized for the event of chest pain, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain. ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:28:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Feb 2021 21:59:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Feb 2021 21:37:06
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 21:36:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 21:36:34
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Feb 2021 21:36:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	19 Feb 2021 21:36:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 22:00:18
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	17 Feb 2021 22:00:18
User entered empty; reason for change Data Entry Error	Naqib Ahmad (b) (4)	17 Feb 2021 22:00:18
	(b) (4)	
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	17 Feb 2021 21:59:01
User entered 'Yes (Y)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

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)	30 Mar 2021 08:39:45
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).		26 Mar 2021 18:09:36
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		26 Mar 2021 18:09:32
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Records are still pending' (Site from Safety).	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 17:33:56
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Records are still pending' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:33:47
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 'Waiting for hospital records' (Site from System).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:33:35

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:27:39
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).		26 Feb 2021 21:27:28
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		19 Feb 2021 21:37:06
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		19 Feb 2021 21:37:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Feb 2021 21:37:06
User entered '1' reason for change: Data Entry Error Naqib Ahmad	(b) (4)	19 Feb 2021 21:37:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	17 Feb 2021 21:59:01
User closed query 'Requires inpatient or prolongation System 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).		17 Feb 2021 21:59:01
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		17 Feb 2021 21:59:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

1717 of 2008

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Naqib Ahmad (b) (4)	17 Feb 2021 21:59:01
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).	(b) (4) System	17 Feb 2021 21:58:25
User entered '1'	Naqib Ahmad (b) (4) (b) (4)	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '21 Nov 2020'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query ' Please send any relevant laboratory and diagnostic test results 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). Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:59:36
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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).		05 Apr 2021 14:57:50
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		02 Apr 2021 22:50:02
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).		02 Apr 2021 22:46:13
User signature succeeded.		26 Mar 2021 18:09:39
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'This will be updated when records are received' (Site from Safety).	Mary Beth Manning (b) (4) Cassie Uminski (b) (4) (b) (4)	26 Mar 2021 13:18:49
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 17:34:09
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	26 Feb 2021 21:29:04
		17 Feb 2021 21:58:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

1720 of 2008

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of study drug was given on 04 Sep 2020, please update the action taken with study drug from none to not applicable. If study drug has been given since 04 Sep 2020, please update the EDC accordingly. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:09:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
Query 'PV Query: As the last dose of study drug was given on 04 Sep 2020, please update the action taken with study drug from none to not applicable. If study drug has been given since 04 Sep 2020, please update the EDC accordingly. ' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4)	25 Mar 2021 17:30:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 17:29:39
User opened query 'PV Query: As the last dose of study drug was given on 04 Sep 2020, please update the action taken with study drug from none to not applicable. If study drug has been given since 04 Sep 2020, please update the EDC accordingly. ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 21:29:20
User entered 'None (NONE)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered '0'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:24:24
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).		26 Mar 2021 18:09:52
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
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 'Medical records are still pending' (Site from Safety).	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:34:20
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)	26 Feb 2021 21:29:45
User entered 'I'	Naqib Ahmad (b) (4) (b) (4)	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:24:29
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:39:40
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' answered with 'Medical records are still pending' (Site from DM).	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 17:34:35
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:05:01
User entered 'I'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cassie Uminski (b) (4)	25 Mar 2021 17:29:39
Data Entry Error	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:18:49
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	17 Feb 2021 21:58:25
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = SHOW EVIDENCE OF MEDIASTINAL MASS. 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 05:23:49
User opened query 'PV Query: Please assess if small cell carcinoma should be reported as an additional AE/SAE.' (Site from Safety).		02 Apr 2021 22:48:07
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).		02 Apr 2021 22:47:10
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).		02 Apr 2021 22:45:47
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).		26 Mar 2021 18:10:00
User closed query 'PV Query: Can you confirm whether "pacemaker" in medical history refers to the insertion of a pacemaker, the presence of one in the subject, or both? ' (Site from Safety).		26 Mar 2021 18:09:55
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:18:49

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that the subject had ANGIOGRAM, ECHO, AND PET SCAN. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:08:38
Query 'Per DM CLR: Narrative indicates that the subject had ANGIOGRAM, ECHO, AND PET SCAN. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' answered with 'Please note that medical records are still pending.' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:36:11
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 'Medical records are still pending' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:35:56
Query 'PV Query: Can you confirm whether "pacemaker" in medical history refers to the insertion of a pacemaker, the presence of one in the subject, or both? ' answered with 'Presence of one in the subject' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:35:43
User opened query 'Per DM CLR: Narrative indicates that the subject had ANGIOGRAM, ECHO, AND PET SCAN. However, there are no corresponding Concomitant Procedures record that match the information. Please review and update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:05:17

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. 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)	26 Feb 2021 21:30:05
User opened query 'PV Query: Can you confirm whether "pacemaker" in medical history refers to the insertion of a pacemaker, the presence of one in the subject, or both? ' (Site from Safety).		26 Feb 2021 21:29:56
User entered 'Late entry: subject reports that on November 21, 2020 he had an episode of chest pain, which prompted him to present to the ER. Subject had some associated difficulty breathing, and given his prior hx of MI (heart attack), subject was hospitalized to rule-out another MI. Although his troponin cardiac markers came back elevated, his angiogram, echo, and pet scan came back negative for an MI, but it did show evidence of mediastinal mass, which is presumed to be secondary to lymph node infection (lymphadenopathy).'	Naqib Ahmad (b) (4) (b) (4)	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 21:58:25

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:23:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:23:10
Data point term sent to Coder	System	12 Apr 2021 20:19:04
User entered 'Fever'	Jennifer Gaston (b) (4)	12 Apr 2021 20:18:33
	(b) (4)	

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Apr 2021'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Apr 2021'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Urgent Query: Please confirm if the event (or any other conditions noted in the medical records) should be considered an SAE. Per medical records, the subject was admitted to the medical team. If subject was not hospitalized, please assess if event meets medically significant criteria.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 18:18:55
Query 'PV Urgent Query: Please confirm if the event (or any other conditions noted in the medical records) should be considered an SAE. Per medical records, the subject was admitted to the medical team. If subject was not hospitalized, please assess if event meets medically significant criteria.' answered with 'Data is correct as is ' (Site from Safety).	Jennifer Gaston (b) (4)	26 Apr 2021 16:38:00
User opened query 'PV Urgent Query: Please confirm if the event (or any other conditions noted in the medical records) should be considered an SAE. Per medical records, the subject was admitted to the medical team. If subject was not hospitalized, please assess if event meets medically significant criteria.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:07:29
User entered 'No (N)'	Jennifer Gaston (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

Death

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 20:18:33

US3182166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 20:18:33

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:31:17
DataPoint Verified.		22 Apr 2021 12:23:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 05:05:17
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'corrected' (Site from DM).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 14:02:45
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 04:45:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:56:34

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 18:58:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:58:18
Data point term sent to Coder	System	11 Aug 2020 18:57:32
User entered 'Atorvastatin'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:56:56

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'High Cholesterol'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '80'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:17:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:56:56
User entered 'un Jan 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:56:56

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:56:56
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:56:56

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:56:56

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:56:56

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 18:58:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:58:16
Data point term sent to Coder	System	11 Aug 2020 18:57:34
User entered 'Aspirin'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:57:16

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User closed query 'Per DM CLR: Note, this medication is not usually given for HEART HEALTH. It is used to treat or prevent a condition. Please review and update the indication to reflect the medical condition being prevented. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 04:52:33
Query 'Per DM CLR: Note, this medication is not usually given for HEART HEALTH. It is used to treat or prevent a condition. Please review and update the indication to reflect the medical condition being prevented. Otherwise, provide clarification. ' answered with 'Confirmed correct per investigator' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	16 Sep 2020 13:06:26
User opened query 'Per DM CLR: Note, this medication is not usually given for HEART HEALTH. It is used to treat or prevent a condition. Please review and update the indication to reflect the medical condition being prevented. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 05:21:49
User entered 'Heart Health'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:57:16

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '81'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:18:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:57:16
User entered 'un UNK 2005'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:57:16

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:16
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:57:16

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:57:16

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:57:16

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 23:28:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:28:21
Data point term sent to Coder	System	11 Aug 2020 18:58:36
User entered 'Carvedilol'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:57:53

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Hypertension/Coronary Artery Disease'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '6.25'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:36:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:57:53
User entered 'un Jan 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:57:53

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:57:53
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 18:57:53

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:57:53

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:57:53

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 21:11:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:11:23
Data point term sent to Coder	System	11 Aug 2020 18:59:37
User entered 'Ticagrelor'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:58:49

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Coronary Artery Disease'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '90'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:18:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:58:49
User entered 'un Jan 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:58:49

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:58:49
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 18:58:49

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:58:49

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:58:49

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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)	11 Aug 2020 19:00:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:00:11
Data point term sent to Coder	System	11 Aug 2020 18:59:38
User entered 'Albuterol'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:59:35

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Chronic obstructive pulmonary Disease'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '2'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'puff (PUFF)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:36:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:59:35
User entered 'un UNK 2011'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:59:35

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:35
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:59:35

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:59:35

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:59:35

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 19:02:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:02:15
Data point term sent to Coder	System	11 Aug 2020 19:00:39
User entered 'Fluoxetine'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:59:58

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Depression'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '10'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:36:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:59:58
User entered 'un UNK 2010'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 18:59:58

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 18:59:58
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:59:58

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:59:58

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:59:58

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 15:38:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:38:50
Data point term sent to Coder	System	16 Sep 2020 13:08:03
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	16 Sep 2020 13:07:37
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'Updated' (Site from System).	Cassie Uminski (b) (4) (b) (4)	16 Sep 2020 13:07:37
User entered 'OCUVITE (vitamin c, vitamin d, vitamin e, zinc, copper, omega 3 fatty acids, lutein, zeaxanthin isomers)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	16 Sep 2020 13:07:32
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:18:17
Data point term sent to Coder	System	11 Aug 2020 19:00:39
User entered 'Ocuville'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:00:21

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Macular degeneration'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM). Query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. answered with 'Correct as is' (Site from DM). User opened query 'Per DM CLR: Please provide the actual dose for this medication instead the number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM). User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6) Cassie Uminski (b) (4) (b) (4) (b) (4), (b) (6) Cassie Uminski (b) (4) (b) (4)	28 Sep 2020 04:53:41 16 Sep 2020 13:10:17 14 Sep 2020 05:22:07 11 Aug 2020 19:00:21

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:36:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 19:00:21
User entered 'un UNK 2019'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:00:21

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:21
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 19:00:21

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:00:21

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 19:00:21

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 19:02:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:02:15
Data point term sent to Coder	System	11 Aug 2020 19:01:41
User entered 'Fish Oil'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:00:44

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '1200'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 14:36:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 19:00:44
User entered 'un Jan 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:00:44

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Aug 2020 19:00:44
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:00:44

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:00:44

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 19:00:44

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Oct 2020 14:04:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 14:04:35
Data point term sent to Coder	System	26 Oct 2020 14:03:19
Coding entries removed.	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 14:02:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 12:53:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 12:53:17
Data point term sent to Coder	System	12 Oct 2020 12:52:00
User entered 'Tylenol'	Cassie Uminski (b) (4) (b) (4)	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'No (N)'	(b) (4)	12 Oct 2020 12:51:06
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN/HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 08:25:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN/HEADACHE did not meet the AE reporting criteria. ' answered with 'Does not meet AE reporting criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	28 Feb 2021 05:19:01

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN/HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 11:23:15
User entered 'injection site pain/headache' reason for change: Data Entry Error	Amy Maroun (b) (4)	26 Oct 2020 14:02:21
User entered 'Body Aches'	Cassie Uminski (b) (4)	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '500' reason for change: Data Entry Error	(b) (4) Amy Maroun (b) (4)	26 Oct 2020 14:02:21
User entered '1000'	(b) (4) Cassie Uminski (b) (4)	12 Oct 2020 12:51:06
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4)	12 Oct 2020 12:51:06
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	Amy Maroun (b) (4)	26 Oct 2020 14:02:21
User entered 'once daily (QD)'	(b) (4)	
	Cassie Uminski (b) (4)	12 Oct 2020 12:51:06
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4)	12 Oct 2020 12:51:06
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4)	12 Oct 2020 12:51:06
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Amy Maroun (b) (4)	26 Oct 2020 14:02:21
	(b) (4)	
User entered '04 Sep 2020'	Cassie Uminski (b) (4)	12 Oct 2020 12:51:06
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '0'	Cassie Uminski (b) (4)	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'No (N)'	(b) (4)	12 Oct 2020 12:51:06
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Amy Maroun (b) (4)	26 Oct 2020 14:02:21
	(b) (4)	
User entered '09 Sep 2020'	Cassie Uminski (b) (4)	12 Oct 2020 12:51:06
	(b) (4)	

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN/HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 02:11:39
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN/HEADACHE did not meet the AE reporting criteria.' answered with 'Does not meet reporting criteria' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	24 Nov 2020 13:48:34

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN/HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN/HEADACHE did not meet the AE reporting criteria.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Cassie Uminski (b) (4) (b) (4)	05 Nov 2020 14:25:54 12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User entered empty.	System	26 Oct 2020 14:02:21
User entered '1'	System	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User entered empty.	System	26 Oct 2020 14:02:21
User entered '1'	System	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:19
User entered empty.	System	26 Oct 2020 14:02:21
User entered '804 (804)'	System	12 Oct 2020 12:51:06

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
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 19:24:36
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 19:24:36
Data point term sent to Coder	System	11 Nov 2020 19:24:12
User entered 'Influenza vaccine'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'I'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'injection'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'once (ONCE)'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '19 Oct 2020'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '0'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered '19 Oct 2020'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User entered empty.	System	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User entered empty.	System	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:16:20
User entered empty.	System	11 Nov 2020 19:24:04

US3182166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:34:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 12:23:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Feb 2021 02:15:24
	(b) (4)	

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered	System	22 Feb 2021 15:02:03
'USA-US075-2021-MRNA-1273-P301000007'		

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Yes (Y)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Yes (Y)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Jennifer'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Gaston'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'OH'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
Reviewed for Safety.		26 Mar 2021 18:12:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'US'	(b) (4) System	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Mar 2021 18:13:03
User entered '1'	System	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered	System	22 Feb 2021 15:02:03
'USA-US075-2021-MRNA-1273-P301000007'		

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Yes (Y)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Yes (Y)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Jennifer'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Gaston'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'OH'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
Reviewed for Safety.		26 Mar 2021 18:12:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'US'	(b) (4) System	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Mar 2021 18:13:03
User entered '1'	System	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
User entered '22/Feb/2021 10:04'	System	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
Reviewed for Safety.		26 Mar 2021 18:12:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered	System	22 Feb 2021 15:02:03
'USA-US075-2021-MRNA-1273-P301000007'		

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Yes (Y)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Yes (Y)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'No (N)'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User entered 'Toby' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Jennifer'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
Un-reviewed for Safety.	Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User entered 'Briskin' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	15 Apr 2021 14:56:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'Gaston'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered '3619 Park East Drive Suite 300'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered 'Beachwood'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 15:04:33
User entered 'OH'	System	22 Feb 2021 15:02:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	15 Apr 2021 20:00:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:04:16
User entered '44122'	Cassie Uminski (b) (4) (b) (4)	15 Apr 2021 14:56:45

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
Reviewed for Safety.		26 Mar 2021 18:12:46
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:24:31
User entered 'US'	(b) (4) System	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Mar 2021 18:13:03
User entered '1'	System	22 Feb 2021 15:04:40

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered '26/Mar/2021 18:13'	System	26 Mar 2021 18:13:03

US3182166

Folder: SAE USA-US075-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:04:16
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:50
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 18:13:03